

Evaluation of the Efficacy of Systemic Ornidazole as an Adjunct to Scaling and Root Planning in Chronic Periodontitis Patients- A Clinical Study

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Abstract

Background: The purpose of this study is to evaluate the adjunctive clinical effects of systemic administration of ornidazole along with the scaling and root planning in cases of generalized chronic periodontitis.

Method: Thirty patients with a minimal of 3 to 4 periodontal pockets in each quadrant with probing pocket depth of 5 to 7 mm were selected. Of the 30 patients selected for the study, 15 patients were assigned under group A for where scaling and root planning was done. The other 15 patients were assigned to group B, where scaling and root planning was combined with systemic administration of Ornidazole. The clinical outcomes evaluated were plaque index, gingival index, clinical attachment level and probing pocket depth at baseline, 1 week and three months.

Results: By the three months, there was a decrease in the probing depth scores as well as clinical attachment loss in both the control as well as the test group. However, there was a greater decrease in the probing depth scores in Group B i.e., test group, and this decrease in the test group (Group B) was statistically significant ($p < 0.05$). Also, there was a decrease in the clinical attachment level scores in both the control as well as the test group. However, there was a greater decrease in the clinical attachment level scores both at 1 week and 3 months in Group B i.e., test group, and this decrease in the test group (Group B) was statistically significant ($p < 0.05$).

Conclusion: The systemic use of ornidazole when used in conjunction with initial periodontal treatment consisting of scaling and root planning in chronic periodontitis, achieves significantly better clinical results than initial periodontal treatment alone.

Keywords: Non-surgical therapy, ornidazole, periodontal disease, root planing, scaling.

Introduction

Periodontitis is a destructive, inflammatory disorder elicited by plaque bacteria. Current Studies have shown that relatively specific sub gingival micro flora are associated the etiology of various periodontal diseases. The healthy gingival sulcus harbours relatively few cells usually of the genera Actinomyces and Streptococcus. The development of the gingivitis is accompanied by a substantial increase in Gram negative organisms. [1]

The micro biota of deep periodontal pockets may consist of high proportions or Spirochetes, Actinobacillus Action my cetes, a small non-motile gram negative capnophilic rod and a number of gram-negative anaerobic rods, of which Porphyromonasgingivalis, Prevotella intermedia and Bacteroides Forsythia are considered important pathogens. (Winkel ET al.1988, American Journal of Clinical periodontology). [2]

Mechanical debridement has been the most successful method for the treatment of periodontal diseases. Scaling and root planning induce consistent alterations in the sub gingival ecosystem and hence reduce the proportions of spirochetes and other periodontopathic microorganisms. In spite of these impressive beneficial effects of the mechanical treatment procedures, limited treatment effects have occasionally been reported from clinical practices. [3] Mechanical debridement may fail to remove pathogenic organisms because of their location in sub-epithelial gingival tissue (A. actinomycetemcomitans), crevicular epithelial cells (A. actinomycetemcomitans, P. micros, P. intermedia and P. gingivalis), collagenous substrata (P. gingival is), altered cementum and radicular dentinal tubuli, sub gingival hard deposits or fractions or other anatomic features complicating adequate instrumentation. Moreover, periodontal pathogens

frequently colonizes oral mucosa, tongue dorsum, tonsils and other oral domains and may translocate from non-periodontal sites to periodontal crevices. [4]

Thus, regardless of how thoroughly instrumentation is carried out, some bacteria may remain within soft tissue, readily available to recolonize the pocket. Adjunctive use of a systemic antibiotic allows drug delivery to the entire pocket, with penetration of the epithelium and connective tissue regions, exposing the organisms to the antibiotic. [5]

Systemic antibiotics enter the periodontal tissues and through periodontal pocket via serum and can affect organisms outside the reach of cleaning instruments or topically-infective chemotherapeutics. Systemic antibiotic therapy can also potentially suppress periodontal pathogens residing on the tongue or other oral surfaces, thereby delaying sub gingival decolonization of pathogens. Systemic antibiotics may even be required for eradication of periodontal infections by *A. actinomycetemcomitans* and other pathogens.

It is conceivable therefore, that local and or systemic administration of antimicrobial agents, effective against such pathogens, may enhance the outcome of mechanical therapy. Several antimicrobial agents (e.g. tetracycline, metronidazole, amoxicillin, clindamycin) have been tested for systemic use in periodontal therapy. Metronidazole has been widely used in Britain for 25 years, for a variety of medical and dental conditions. It is of considerable importance in Periodontics because of its activity against obligate anaerobes.

In the group of nitroimidazole compounds ornidazole has emerged as the drug with similar antibacterial properties as metronidazole. Ornidazole [α (chloromethyl)-2-methyl-5-nitroimidazole-1-ethanol] is an antibiotic used for the treatment of anaerobic infections. Comparative pharmacokinetic studies have shown that ornidazole showed increased half-life of elimination from plasma, and administration of the drug could therefore be simplified by less frequent intervals of intake. A recent report provided data to support the hypothesis that ornidazole might be a valuable adjunctive to chemotherapeutic agent in the treatment of chronic periodontitis. [6]

The main objective of the present study is to evaluate the efficacy of the drug Ornidazole, in adjunct to scaling and root planning, in patients suffering from chronic periodontitis. Hence, a clinical study was carried out to evaluate the efficacy of the drug ornidazole having similar properties to that of metronidazole with the following objectives:

1. To evaluate the efficacy of the scaling and root planning (SRP) in the treatment of Chronic Periodontitis.
2. To evaluate the efficacy of the scaling and root planning (SRP) in addition with ornidazole in the treatment of Chronic Periodontitis.
3. To compare the effects of the scaling and root planning (SRP) alone and combined therapy of scaling and root planning (SRP) with ornidazole on clinical parameters in the treatment of Chronic Periodontitis.

Materials and Method

Source of data: A total of 30 patients, with the history of chronic periodontitis, satisfying the inclusion and exclusion criteria were selected from the out-patient department of Periodontics, Rama dental college, Hospital and research centre, Kanpur. Informed consent was taken from all the patients.

Study Design: Of the 30 patients selected for the study, 15 patients were assigned under group A for where scaling and root planning was done. The other 15 patients were assigned to group B, where scaling and root planning was combined with systemic administration of Ornidazole.

Inclusion Criteria

- Patients with generalised chronic periodontitis.
- Patients with age limit 25 to 45 years.
- Patients having minimum of 3 to 4 periodontal pockets in each quadrant with probing pocket depth of 5 to 7 mm.
- Otherwise systemically healthy patients

Exclusion criteria

- Patients with history of antibiotic hypersensitivity particularly with ornidazole, metronidazole and tinidazole
- Patients who have received any periodontal therapy, non-surgical or surgical during past 6 months of baseline examination
- Patients using antibiotic drugs within 6 months of baseline examination.
- Patients using antibacterial mouthwash for the past six months.
- Pregnant and lactating patient.
- Medically compromised patients requiring prophylactic antibiotics.

Clinical Parameters

The following parameters were recorded at baseline, 1 week and 3 months.

- Plaque Index (Silness and Loe, 1964) [7]
- Gingival Index (Loe and Silness, 1963) [8]
- Periodontal pocket depth measurement using Williams graduated probe/UNC15probe.
- Clinical attachment level measurement using Williams graduated probe/UNC15probe

Procedure

After the collection of the plaque samples, both group A and group B patients received scaling and root planning procedure using ultrasonic scalar and curettes, till a hard, smooth and clean surface was obtained. However, group B patient's received systemic administration of ornidazole in addition to scaling and root planning. The group B patients were instructed to take ornidazole, 500 mg, two times daily, for a period of seven days. Oral hygiene instructions were given to each patient. Modified Bass technique of brushing was recommended for all patients. Patients were instructed to brush with bass technique. The patients were recalled and followed up after 1 week and 3 months. The previously mentioned parameters were recorded both at 1 week and 3 months.

Method of Statistical Analysis

The data was analysed using Statistical Package for Social Science (SPSS, V 10.5). The results for each parameter (numbers and percentages) for discrete data and averaged (mean \pm standard deviation) for continuous data were presented in tables. Paired t test was applied to assess the statistical significance between time points within each group. When the data was normal, the student 't' test was used to determine that whether there was a statistical difference between groups in the parameters measured. In all above test P value less than 0.05 was taken to be statistically significant.

Results

The present study was aimed to assess the efficacy of systemic administration of ORNIDAZOLE (500 mg bid for 7 days) in the treatment of chronic periodontitis. A total number of 30 sites from 30 patients, with periodontal pocket depth measuring 5 mm to 7 mm were selected for the study.

The sites selected were divided into:

1. Control site (Group A)-15 sites in number. Treated with scaling and root planning

2. Test Site (Group B) - 15 sites in number. Treated with scaling and root planning followed by systemic administration of Ornidazole.

At the selected sites, the before mentioned clinical parameters were assessed at baseline, 1 week and 3 months.

The results of the study were compiled as follows:

Age Distribution: The age ranged from 25-34 years in Group A and 35-45 years in-group B.(Table 1)

Gender Distribution: Out of the 30 patients, 23 were male and 7 were female patients. In Group A, 80% were male and 20% were female, In Group B 73.3% was male and 26.7% were female. (Table 2)

Plaque Index

Comparison within the groups: In Group A (Control group), Mean plaque scores at Baseline was 1.413, at 1 week was 1.227 and at 3 months was 1.093. Thus, there was a decrease in the mean plaque scores from baseline to 1 week as well as from baseline to 3 months which is statistically significant ($P < 0.05$). In Group B (Test group), Mean plaque scores at Baseline was 1.447, at 1 week was 0.940 and at 3 months was 0.927. Thus, there was a decrease in the mean plaque scores from baseline to 1 week as well as from baseline to 3 months which is statistically significant ($P < 0.05$). (Table 3)

Comparison between the groups: There was a decrease in the plaque index scores in both the control as well as the test group. However, there was a greater decrease in the plaque index score both at 1 week and 3 months in Group B i.e., test group, and this decrease in the test group (Group B) was statistically significant ($p < 0.05$) (Table 4).

Gingival Index:

Comparison within the groups:

In Group A (Control group), Mean gingival scores at Baseline was 1.480, at 1 week was 1.320 and at 3 months was 1.260. Thus, there was a decrease in the mean gingival scores from baseline to 1 week as well as to 3 months which is statistically significant ($P < 0.05$). In Group B (Test group), Mean gingival scores at Baseline was 1.547, at 1 week was 1.153 and at 3 months was 1.040. Thus, there was a decrease in the mean gingival scores from baseline to 1 week as well as to 3 months which is statistically significant ($F < 0.05$). (Table 5).

Comparison between the groups: There was a decrease in the gingival index scores in both the control as well as the test group. However, there was a greater decrease in the gingival index score both at 1 week and 3 months in Group B i.e., test group, and

this decrease in the test group (Group B) was statistically significant ($p < 0.05$) (Table 6).

Probing Depth (in mm)

Comparison within the groups: In Group A (Control group), Mean probing depth at baseline was 6.47, at 1 week was 5.67 and at 3 months was 5.60. Thus, there was a decrease in the mean probing depth from baseline to 1 week as well as to 3 months which is statistically significant ($P < 0.05$). In Group B (Test group), Mean probing depth at Baseline was 6.27, at 1 week was 5.27 and at 3 months was 4.80. Thus, there was a decrease in the mean probing depth from baseline to 1 week as well as from baseline to 3 months which is statistically significant ($P < 0.05$). (Table 7).

Comparison between the groups: There was a decrease in the probing depth scores in both the control as well as the test group. However, there was a greater decrease in the probing depth score both at 1 Week and 3 months in Group B i.e., test group, and this decrease in the test group (Group B) was statistically significant ($p < 0.05$) (Table 8).

Clinical Attachment Level (in mm)

Comparison within the groups: In Group A (Control group), Mean clinical attachment level at Baseline was 10.40, at 1 week was 9.67 and at 3 months was 9.60. Thus, there was a decrease in the mean clinical attachment level from baseline to 1 week as well as to 3 months which was statistically significant ($P < 0.05$). In Group B (Test group), Mean clinical attachment level at Baseline was 10.27, at 1 week was 9.00 and at 3 months was 8.60. Thus, there was a decrease in the mean clinical attachment level from baseline to 1 week as well as from baseline to 3 months which was statistically significant ($P < 0.05$). (Table 9)

Comparison between the groups: There was a decrease in the clinical attachment level scores in both the control as well as the test group. However, there was a greater decrease in the clinical attachment level scores both at 1 week and 3 months in Group B i.e., test group, and this decrease in the test group (Group B) was statistically significant ($p < 0.05$). (Table 10)

Discussion

The purpose of this case-control study was to evaluate the efficacy of Onidazole as an adjunct to mechanical debridement among the chronic periodontitis patients. The clinical and microbiological effects of the drug have been

compared with SRP and systemic Ornidazole and SRP alone.

The objective of periodontal treatment is to eliminate or reduce the proportion of periodontal pathogens to a level manageable by the host. Systemically antimicrobial therapy is based on the premise that the antimicrobial agent in the periodontopathogenic environment should reach the necessary concentration to selectively eliminate the pathogen. Scaling and root planning are one of the most commonly utilized procedures for the treatment of periodontal disease and has been used as the gold standard treatment.

Observation made in this control group study showed that there was statistically significant reduction in plaque index Scores, gingival index scores. Control group mean plaque score decreased from baseline (before SRP) to one week after SRP (from 1.413 to 1.227), and up to three months (1.093). There was statistically significant decrease of gingival index score from baseline (before SRP) to one week (from 1.480 to 1.320) and up to 3 months (1.260). In, control group mean probing depth decreased from baseline (before SRP) to one week after SRP (from 6.47 mm to 5.67 mm), and up to 3 months (5.60 mm). There was statistically significant decrease of mean probing depth and gain in mean clinical attachment level from baseline (before SRP) to one week (from 10.440 mm to 9.67 mm) and up to 3 months (9.60 mm). This study showed that mechanical treatment alone is clinically effective which is in accordance with the various studies (Egelberg J, Hung H Dougless.) [9].

The additional administration of antibiotics to the mechanical treatment have been advocated for the treatment of advanced periodontal lesions (Lindhe 1983). [10] This combined regimen of the mechanical and systemic antibiotic therapy may provide more successful modality to reduce the subgingival periodontopathic microorganisms (Genco 1981). [11] The results observed in this study when systemic administration of Ornidazole 500 mg for 7 days showed significant decrease of mean plaque score, mean gingival score, reduction in probing pocket depth and relative attachment level from baseline to one week and from one week to 3 months with greater improvement in the test group. On comparing both the control and test group, an interesting observation was made in the test group receiving the drug Ornidazole. Clinical parameters showed statistically significant decrease in the mean gingival scores, mean plaque score, probing pocket depth and relative attachment level from baseline to 3 months ($P < 0.05$).

The result of the present study showing marked reduction in Pocket depth and gain in clinical

attachment level drawing the monitoring period between baseline to 1 week and from 1 week to 3 months period. This can be considered as a sign of favourable tissue response to the adjunct effect of ornidazole which is statistically significant.

Findings related to clinical improvement with drug Ornidazole are in accordance with the study carried on by Mombelli A, Gusberti FA, Lang NP; [6] indicating a significant improvement of clinical measurement in patients with advanced disease who received SRP and concomitant with Ornidazole and metronidazole therapy in accordance with the study carried on by Loesche W.J, Giordano JR, Hujoel P, Schwarcz J, Smith BA.[12]

Clinical improvement in plaque score, gingival score and the decrease in pocket probing depth as reflected by an increase in tissue resistance, by decrease in penetration of the probe. This could be due to the formation of an epithelial attachment to the tooth surface and occasionally formation of the new connective tissue showing favourable tissue response to the Ornidazole therapy. (Fowler 1982). [13]

It is known that sub gingival bacteria exist within a bio film, which may greatly enhance their resistance to antibiotics in comparison with planktonic bacteria. This resistance becomes more pronounced as the bio films ages. At any given time within in bio film communities, a plethora of phenotypes is represented for each component species. The breadth of phenotypes represented reflects the extent of the chemical heterogeneity within the bio film. Thus, the outcome of any attempt to eliminate a biofilm community by antimicrobials often reflects only the susceptibility of the most resistant phenotype represented. Therefore, it could be speculated that the concentration of Ornidazole in this study reached levels above the threshold needed to suppress the pathogens in the bio film community and proved to be effective against multispecies bio film communities as the micro biota of the periodontal pocket. Thus, showing the improvement in all the clinical parameters. As stated earlier, the results of the present study reinforced the significance of the Ornidazole administration along with the mechanical treatment. The above data show that, in chronic periodontitis patients-for deep periodontal pockets; sub gingival debridement plus systemic Ornidazole antibiotic therapy provided better clinical results than scaling and root planning alone.[14]

Conclusion

In conclusion, Ornidazole when combined with subgingival debridement showed a substantial clinical improvement thereby indicating that it is effective in

the treatment of chronic periodontitis where anaerobic bacteria are predominant. The above data show that, in chronic periodontitis deep periodontal pockets, sub gingival debridement plus systemic Ornidazole antibiotic therapy provided better clinical results than SRP alone. Within the limits of present study, one can draw a conclusion that, the drug ORNIDAZOLE is more effective in patients with chronic periodontitis. The efficacy of the drug ORNIDAZOLE is proved by significant improvement in clinical parameters.

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Table -1: Mean Age Distribution of the Study Group

Group	N	Mean Age	Std. Deviation	Minimum	Maximum	't' Value	'p' Value
Control	15	35.73	6.088	25	45	5.945	0.021
Test	15	30.93	4.590	25	38		

(P <0.05)

Table -2: Gender Distribution among the Study Group

Group	Gender		Total	Chi-Square Value	df	'p' value
	Male	Female				
Control	12	3	10	0.186	1	0.666
	80.0%	20.0%	100.0%			
Test	11	4	20			
	73.3%	26.7%	100.0%			
Total	12	18	30			
	76.7%	23.3%	100.0%			

(P <0.05)

Table -3: Intra-Group Comparison of Mean Plaque Index

Group	Visit	N	Mean Plaque Index (in mm)	Std. Deviation	Minimum	Maximum	F	'p' Value
Group A	Baseline	15	1.413	0.0743	1.2	1.5	41.104	0.000
	Week 1	15	1.227	0.0961	1.0	1.4		
	3Months	15	1.093	0.1163	0.9	1.3		
Group B	Baseline	15	1.447	0.0834	1.3	1.6	105.929	0.000
	Week 1	15	0.940	0.1242	0.8	1.1		
	3Months	15	0.927	0.1223	0.7	1.2		

(P <0.05)

Table -4: Inter-Group Comparison of Mean Plaque Index

Visit	Group	N	Mean Plaque Index (in mm)	Std. Deviation	Minimum	Maximum	't' value	'p' value
Baseline	Group A	15	1.413	0.0743	1.2	1.5	1.336	0.258
	Group B	15	1.447	0.0834	1.3	1.3		
Week 1	Group A	15	1.227	0.0961	1.0	1.4	49.973	0.000
	Group B	15	0.940	0.1242	0.8	1.1		
3 Months	Group A	15	1.093	0.1163	0.9	1.3	14.632	0.001
	Group B	15	0.927	0.1223	0.7	1.2		

(P <0.05)

Table -5: Intra-Group Comparison of Mean Gingival Index

Group	Visit	N	Mean Gingival Index (in mm)	Std. Deviation	Minimum	Maximum	F	'p' value
Group A	Baseline	15	1.480	0.1146	1.3	1.7	12.652	0.000
	Week 1	15	1.320	0.1014	1.1	1.5		
	3Months	15	1.260	0.1502	1.0	1.5		
Group B	Baseline	15	1.547	0.0834	1.4	1.7	75.420	0.000
	Week 1	15	1.153	0.1187	1.0	1.4		
	3Months	15	1.040	0.1454	0.8	1.3		

(P <0.05)

Table -6: Inter-Group Comparison of Mean Gingival Index

Visit	Group	N	Mean Gingival Index (in mm)	Std. Deviation	Minimum	Maximum	't' value	'p' value
Baseline	Group A	15	1.480	0.1146	1.3	1.7	3.318	0.079
	Group B	15	1.547	0.0834	1.4	1.7		
Week 1	Group A	15	1.320	0.1014	1.1	1.5	17.090	0.000
	Group B	15	1.153	0.1187	1.0	1.4		
3Months	Group A	15	1.260	0.1502	1.0	1.5	16.608	0.000
	Group B	15	1.040	0.1454	0.8	1.3		

(P <0.05)

Table -7: Intra-Group Comparison of Mean Probing Depth

Group	Visit	N	Mean Probing depth (mm)	Std. Deviation	Minimum	Maximum	F	'p' value
Group A	Baseline	15	6.47	0.516	6	7	7.09	0.002
	Week 1	15	5.67	0.724	5	7		
	3 Months	15	5.6	0.828	4	7		
Group B	Baseline	15	6.27	0.594	5	7	17.454	0
	Week 1	15	5.27	0.594	4	6		
	3 Months	15	4.8	0.862	4	7		

(P <0.05)

Table -8: Inter-Group Comparison of Mean Probing Depth

Group	Visit	N	Mean Clinical Attachment level (mm)	Std. Deviation	Minimum	Maximum	F	'p' Value
Group A	Baseline	15	10.4	0.737	9	11	3.816	0.03
	Week 1	15	9.67	0.9	8	11		
	3 months	15	9.6	0.986	8	11		
Group B	baseline	15	10.27	0.704	9	11	13.811	0
	Week 1	15	9	0.845	7	10		
	3 months	15	8.6	1.121	6	10		

(P <0.05)

Table -9: Intra-Group Comparison of Mean Clinical Attachment Level

Visit	Group	N	Mean Probing Depth (Mm)	Std. Deviation	Minimum	Maximum	'T' Value	'P' Value
Baseline	Group A	15	6.47	0.516	6	7	0.969	0.333
	Group B	15	6.27	0.594	5	7		
Week-1	Group A	15	5.67	0.724	5	7	2.739	0.109
	Group B	15	5.27	0.594	4	6		
3 Months	Group A	15	5.6	0.828	4	7	6.72	0.015
	Group B	15	4.8	0.862	4	7		

(P <0.05)

Table -10: Inter-Group Comparison of Mean Clinical Attachment Level

Visit	Group	N	Mean clinical Attachment level(mm)	Std. Deviation	Minimum	Maximum	't' Value
Baseline	Group A	15	10.4	0.737	9	11	0.257
	Group B	15	10.27	0.704	9	11	
Week 1	Group A	15	9.67	0.9	8	11	4.375
	Group B	15	9	0.845	7	10	
3 months	Group A	15	9.6	0.986	8	11	6.731
	Group B	15	8.6	1.121	6	10	

(P <0.05)