

Original Research Article

Comparative evaluation of satranidazole and ornidazole effectiveness in the treatment of chronic periodontal diseases along with mechanical debridement

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ABSTRACT

Background: Periodontitis is a common chronic inflammatory dental disease, which occurs due to the existence of pathogenic microorganisms within the gingival plaque and lead to the formation of periodontal pocket. This study was aimed to evaluate the effectiveness of satranidazole and ornidazole in the treatment of chronic periodontal diseases along with mechanical debridement.

Methods: Forty subjects were randomly selected to access the effectiveness of selected drugs on the basis of clinical and microbiological investigations over a period of 14 days. Six Ramfjord teeth (i.e. 16, 21, 24, 36, 41 and 44) were examined for investigating clinical parameters such as gingival inflammation, pocket depth and bleeding on probing. Microbiological investigations were carried out to examine the presence of gram positive (cocci and bacilli), gram negative (cocci and bacilli) and spirochaetes.

Results: A substantial progress was recorded in treating gingival inflammation, pocket depth and bleeding on probing. The results of microbiological investigations suggest that the satranidazole and ornidazole were equally effective when used alone and with scaling and root planning in reducing microbial infections. The results indicated a significant ($p < 0.0001$) effect of model drugs on clinical and microbiological parameters in different study subjects at baseline (pre-treatment), and 7 days and 14 days post treatment.

Conclusions: The results concluded that ornidazole is better than satranidazole in treating periodontal diseases.

Keywords: Bleeding on probing, Gingival inflammation, Periodontitis, Pocket depth

INTRODUCTION

Periodontitis is a common and widespread chronic inflammatory dental disease, which occurs due to the existence of pathogenic microorganisms within the gingival plaque and lead to the formation of periodontal pocket.¹⁻³ Gram negative anaerobic bacteria such as *Prevotella intermedia*, *Porphyromonas gingivalis*, *Bacteroides*, *Fusobacterium species* and *Actinobacillus actinomycetem-comitans* are commonly associated with periodontal infections.^{4,7} Swollen and bleeding gums are early signs of bacterial infection.⁸ It is estimated that the

periodontitis affects approximately 50% of adults and over 60% of over 65 year olds, with severe periodontitis impacting 10-15% of the populations.³ In order to eliminate or control the disease and arrest further periodontal tissue destruction, periodontal pockets need repeated sub gingival mechanical debriment/cleansing.

The adjunctive use of antibiotics such as satranidazole and ornidazole has been reported as effective for the suppression of periodontal pathogens.^{9,10} Ornidazole have a spectrum of activity against strictly anaerobic microorganisms and have been used successfully in the

treatment of periodontal diseases. The meta-analysis study of the effect of systemic satranidazole as an adjunct to scaling and root planning conclude that its use may offer benefits in the treatment of adult periodontitis.¹¹

In case of satranidazole 2^oC of the imidazole ring is connected through nitrogen to a substituted imidazolidinone moiety which differs it from other imidazolidinone derivatives such as metronidazole and ornidazole. Satranidazole possesses similar activity as metronidazole against cecal amebiasis in experimental animal models such as mouse and hamster.¹² Comparative pharmacokinetic studies have shown that satranidazole have a longer half-life ($t_{1/2}$ 14h) and higher blood levels when compared to other nitroimidazole antibiotic like metronidazole ($t_{1/2}$ 8.7h).^{12,14}

This leads to decrease in dose frequency of this drug when compared to metronidazole and ornidazole ($t_{1/2}$ 14.5h).¹⁵ Satranidazole exhibits significantly higher plasma concentrations when compared to the metronidazole at 1 and 2h post dose. It has been reported that higher plasma and liver concentrations of satranidazole and greater intrinsic potency probably contribute to superior amoebicidal activity when compared to the mertonidazole.¹⁶ Satranidazole is more active against aerobic, microaerophilic, and anaerobic bacteria than mertonidazole.¹⁷

These factors combined with its greater potency are believed to contribute to its better therapeutic response. It is evident that ornidazole is more effective in the treatment of periodontal infections caused by gram positive and gram negative bacteria and spirochaetes when compared to the metronidazole.¹⁸ This kind of profile of ornidazole over metronidazole against anaerobic bacteria has been reported earlier in routine susceptibility laboratory tests.¹⁹

Thus, considering the above reported facts, in the present work an attempt was made to evaluate the effectiveness of satranidazole and ornidazole in the treatment of chronic periodontal diseases along with mechanical debridement. Clinical and microbiological parameters were used to compare the effectiveness for five modes of therapy.

METHODS

The study was performed on 40 subjects, irrespective of gender, in the age group of 18-46 years, attending the post graduate clinic of the department of periodontics, Faculty of dental sciences in collaboration with the department of microbiology, King George's Medical University, Lucknow (Formerly King George Medical College, Lucknow). Table 1 presents the criteria for inclusion and exclusion of study subjects.

Forty subjects were randomly taken into three groups on the basis of treatment executed (Table 2). The group A

and B were further subdivided into three subgroups, including eight subjects each. Group A: Subjects were subjected to scaling and root planning (SRP) in addition to drugs administration. Group B: Only drugs were given orally without SRP. Group C or placebo: only SRP was performed.

Table 1: Inclusion and exclusion protocol followed for the selection of study subjects.

Subjects with modest to severe inflamed gingival	
Inclusion criteria	Systemically healthy subjects having no any periodontitis is noticed
	No root planning or scaling within the past 3 months
	Subjects who gave assent
Exclusion criteria	Subjects with moderate to severe periodontitis with pocket depth ≥ 5 mm
	Mobile and carious teeth
	Pregnant or lactating females
	Suffering from any physical disability
	Individuals on antibiotics and/or antioxidants therapy from 3 months prior to treatment
	Subjects with chain smoking or tobacco chewing habits, alcohol consumers and drug abusers
	Subjects with a history of intolerance to nitroimidazole drugs

Table 2: Study protocol of periodontitis subjects used for clinical and microbiological investigations (n = 8).

Treatment groups	Treatment
Group A	Subgroup: A1 Drug X + SRP
	Subgroup: A2 Drug Y + SRP
Group B	Subgroup: B1 Drug X only
	Subgroup: B2 Drug Y only
Group C (Placebo)	- SRP

Clinical parameters

Clinical parameters were examined at baseline, after 7 days and 14 days post treatment. Six Ramfjord teeth (i.e. 16, 21, 24, 36, 41 and 44) were examined for investigating clinical parameters. Following clinical parameters were considered in the evaluation of effectiveness of the drugs

Investigation of gingivitis status

The gingival status was clinically examined using Ramfjord gingivitis index using scale as: 0 for no inflammation, 1 for mild to moderate inflammatory changes not extending all around the tooth, 2 for mild to moderately severe gingivitis extending all around the tooth, and 3 severe gingivitis characterized by redness, swelling tendency to bleed and ulceration.

Investigation of pocket depth

Probing pocket depth was measured by University of North Carolina Probe 15 (UNC 15 probe) on each surface of the tooth (Mesial, mild facial, distal and mild-lingual). A thin shank of this prob allows access into the tight fibrotis saculi and it is suitable for use in deep periodontal pockets. In the present investigation, all the measurements were rounded to the nearest millimetre.

Investigation of bleeding on probing (BOP)

BOP was measured using the papillary bleeding index as: 0 for no bleeding, 1 for bleeding some seconds after probing, 2 for bleeding immediately after probing, and 3 for bleeding on probing towards the marginal gingival.

Scaling and root planning

Root planning and ultrasonic scaling followed by the baseline recordings of clinical parameters were carried out using hand curettes in group A and C subjects. Special attention was devoted to the selected teeth and lower incisors.

Preparation of drug samples

Empty hard gelatine capsules (224 for satranidazole and ornidazole and 112 for placebo) of "0" size and same colour were used for the study. Satranidazole tablet (500mg) and ornidazole tablet (500mg) were crushed individually into fine powder using clean and dry mortar and pestle and filled into the capsule shell. Glucose was filled within the placebo capsules. The filled hard gelatine capsules were placed in four different containers and randomly labelled as 1, 2, 3 and 4 by a person other than the investigators. The drugs were administered orally for 7 days without missing the dose.

Collection of samples for microbial analysis

Before initiating the treatment Gingival Crevicular Fluid (GCF) samples were collected, after 7 days and 14 days of post treatment from each individual. Samples were collected casually from the facial surfaces of lower incisors. In periodontal pocket a standard size (No. 15) paper point was placed for 2 min. After 2 min, the paper point was withdrawn and kept in microbial free Eppendorf containing sterile normal saline (1ml). For further microbiological analysis, the samples were instantaneously taken to the department of microbiology.

Microbiological analysis

The samples were centrifuged at 830 g with rotar radius 8.25 (Beckman F241.5 in microfuge 22R) and after centrifugation the settled material was suspended in 100µl saline solution. Further, 10µl of suspension was utilised for preparation of smear sample. Five fields in oil immersion were tested for bacterial count and recorded as

percentage count. The identification and classification of bacterial species in two major groups (gram positive and gram negative) was carried out using Gram's staining technique. The smear samples were examined for the presence of gram positive (cocci and bacilli), gram negative (cocci and bacilli) and spirochaetes.²⁰ Fontana's technique was used to carry out staining of spirochaetes.²¹

Statistical analysis

In case of clinical parameters, two-way ANOVA was applied to determine the difference between and within the groups, whereas for the analysis of microbiological data one-way ANOVA was carried out. Differences between the data were considered significant at $p < 0.0001$. All the calculations were performed using GraphPad Prism v5 (GraphPad Prism Software Inc., San Diego, California).

RESULTS

In the present investigation, we made an attempt to analyze the comparative effectiveness of ornidazole and satranidazole for mechanical debridement on the basis of various clinical and microbiological examinations. The study evaluated the significance of a particular treatment on inter and intra groups in a periodic manner. The outcomes of various clinical parameters such as gingival score, pocket depth (mm) and BOP at baseline, 7 days post treatment, and 14 days post treatment for different subgroups (i.e. A1, A2, B1, B2, and C) are presented in Figure 1.

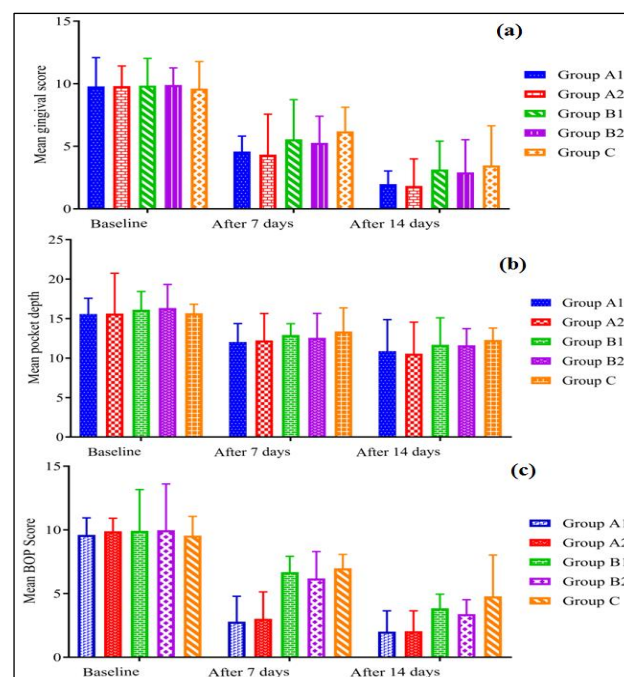


Figure 1: Results of mean pocket depth in mm (a), mean gingival score (b), and mean BOP score at different time intervals for the subjects of different groups. The data presents mean±SEM (n = 8).

In this study, the score of each clinical parameter for individual subject in group A1 was computed by dividing the number of teeth examined. The results suggest that the gingival scores were in the ranges of 8.73 to 10.31, 4.22 to 5.33, and 1.62 to 2.21, respectively at baseline, after 7 days and 14 days post treatment.

In case of group A₂ subjects, the gingival score was in ranges from 9.30 to 10.10, 3.63 to 5.15 and 1.59 to 2.14, respectively at baseline, after 7 days and 14 days post treatment. The gingival score in group B1 was in the range of 7.95 to 11.33, 5.17 to 6.51, and 2.52 to 4.07 at baseline, after 7 days post treatment, and after 14 days post treatment. The clinical data for the subjects of group

B2 suggested that the gingival score was in the range of 9.00 to 10.33.

This value was decreased to 4.83 to 5.83 and 2.42 to 4.10, respectively after a period of 7 days and 14 days of treatment. In case of the subjects of group C, the value of gingival score was in the range of 8.63 to 9.97 at baseline. After 7 days of the therapy this score was decreased to a minimum of 5.31 and maximum of 6.11. At the end of study (days 14) the score was further decreased to 2.82 to 3.46. The results of gingival score of the treated groups are presented in Figure 1a. The treatments had significant ($p < 0.0001$) effect on the mean gingival score of different treated groups (Table 3).

Table 3: Results of two-way ANOVA on the data obtained from pocket depth, gingival score, and BOP score at different time intervals for the subjects of different groups.

Source of variation	Sum of square	Degree of freedom	Mean squares	Calculated F	Remark
Gingival score ($p < 0.0001$)					
CSS	21.74	4	5.436	F (4, 105) = 0.1316	
RSS	1043	2	521.7	F (2, 105) = 12.63	Significant
ESS	4339	105	41.32		
Pocket depth ($p < 0.0001$)					
CSS	19.52	4	4.879	F (4, 105) = 0.06824	
RSS	426.2	2	213.1	F (2, 105) = 2.98	Non-significant
ESS	7508	105	71.5		
BOP score ($p < 0.0001$)					
CSS	110.8	4	27.7	F (4, 105) = 0.8263	
RSS	914.9	2	457.5	F (2, 105) = 13.65	Significant
ESS	3520	105	33.52		

CSS: Column sum of squares, RSS: Raw sum of squares, ESS: Error sum of squares

The results show that the pocket depth score of group A1 subjects ranges between 13.51 to 15.83, 10.42 to 13.57, and 9.57 to 11.53, respectively at baseline, after 7 days post treatment, and 14 days post treatment. In case of group A₂ subjects, the pocket depth score of ranges between 13.30 to 15.23, 10.15 to 12.21, and 8.11 to 11.92, respectively at baseline, after 7 days and 14 days post treatment. The pocket depth score of group B1 ranges between 14.30 to 16.14 at baseline, 9.21 to 13.73 after 7 days, and 11.08 to 12.11 after 14 days of the treatment. The pocket depth score in group B2 ranges from 14.82 to 17.57 at baseline, 11.12 to 12.31 after 7 days and 11.31 to 12.87 after 14 days. The pocket depth score in group C subjects was from 14.88 to 16.80 at baseline, 11.54 to 13.22 after 7 days and 11.04 to 12.73 after 14 days. The results of gingival score of the treated

groups are presented in Figure 1b. The results suggest that the difference in pocket depth was non-significant ($p < 0.0001$) (Table 3).

The BOP score of group A1 subjects at baseline was 9.42 to 10.00. After 7 days it was reduced to the range of 2.52 to 3.17, which was further decreased to the range of 2.13 to 3.11 at the end of study (day 14). The BOP score values for group A₂ subjects were 9.51 to 11.24, at baseline. Post treatment the BOP score reduced to 5.48 to 8.27 and 3.52 to 4.71, respectively after 7 days and 14 days. In case of group B2 subjects, the BOP score at baseline was in the range of 9.13 to 11.05. This was decreased to 5.21 to 7.15 and 2.79 to 5.13, respectively after a period of 7 days and 14 days post treatment. The BOP score for group C at baseline was in the range from 8.95 to 10.43. The BOP score of group C subjects was

decreased to 5.84 to 7.69 and 3.79 to 5.95, respectively after 7 days and 14 days post treatment. The statistical treatment of mean data obtained from groups suggests a significant ($p < 0.0001$) decrease in BOP score (Table 3). The results of gingival score of the treated groups are presented in Figure 1c.

BOP is an indicator of tissue inflammatory response to bacterial pathogens.²² It has been reported that the bleeding reflects histological, clinical and bacteriological alterations related to the periodontal conditions. Bleeding is an earlier sign of gingivitis than visual sign of inflammation such as redness and swelling.²³ Figure 2

presents the results of intra group comparison of gingival score, pocket depth, and BOP score at baseline, and 7 day and 14 day post treatment.

The gingival score and BOP score were reduced significantly ($p < 0.0001$) from baseline to 7 day post treatment and from 7 day post treatment to 14 day post treatment as the calculated F values for all the treated groups were more than the table values at their corresponding degree of freedom. However, the effect on pocket depth score was non-significant. The level of statistical significance for intra group comparison was calculated using one way ANOVA.

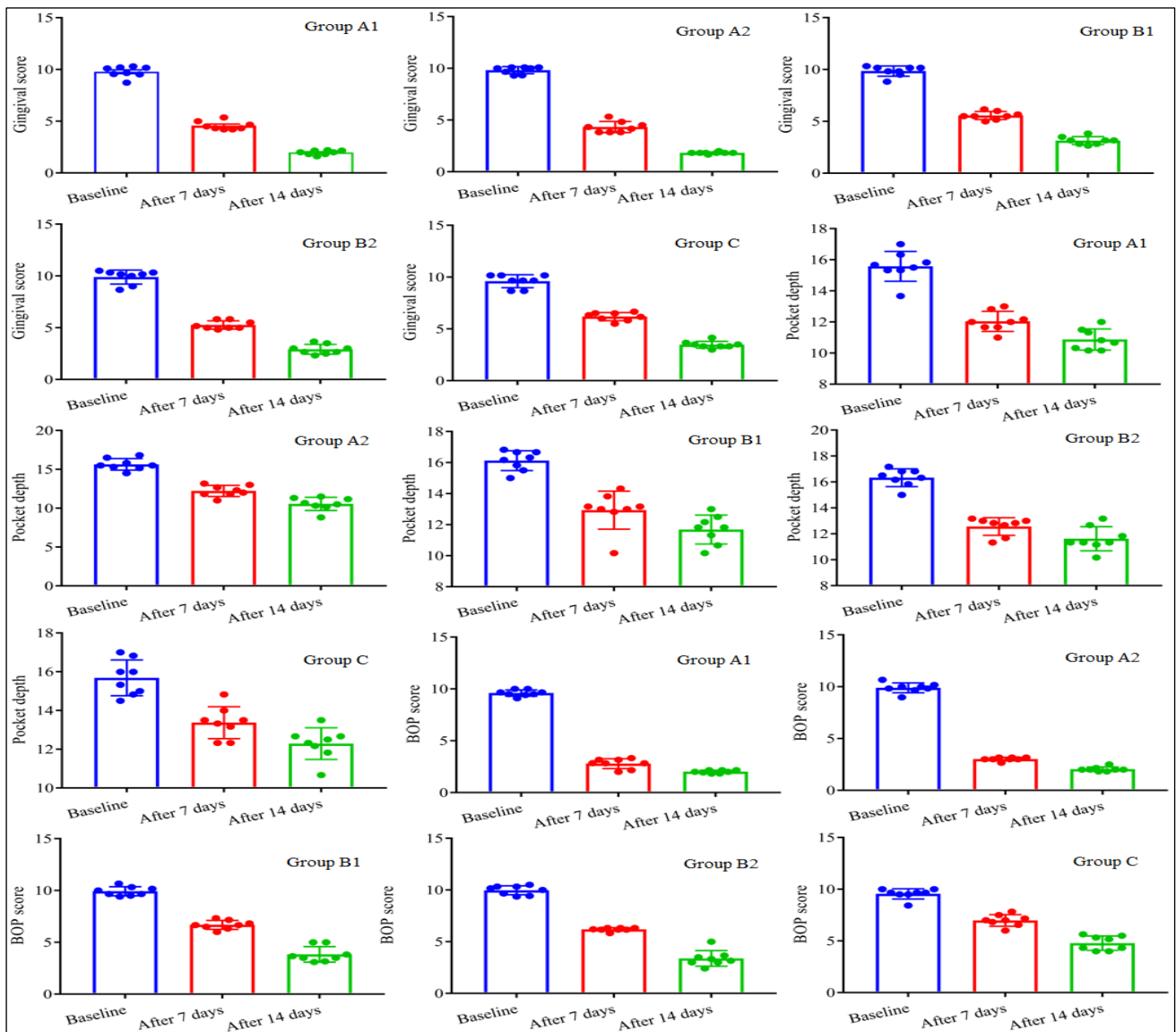


Figure 2: Results of intra group comparative study showing gingival score, pocket depth, and BOP score in different treatment groups at baseline, 7 days post treatment and 14 days post treatment Data presents mean±SEM (n = 8).

Figure 3 presents the results of inter group comparison of gingival score, pocket depth, and BOP score at baseline,

and 7 day and 14 day post treatment. The gingival score, pocket depth score and BOP score were reduced

significantly ($p < 0.0001$) from baseline to 7 day post treatment and from 7 day post treatment to 14 day post treatment as the calculated F values for all the treated groups were more than the table values at their corresponding degree of freedom (Table 3). The level of statistical significance for intra group comparison was calculated using two-way ANOVA.

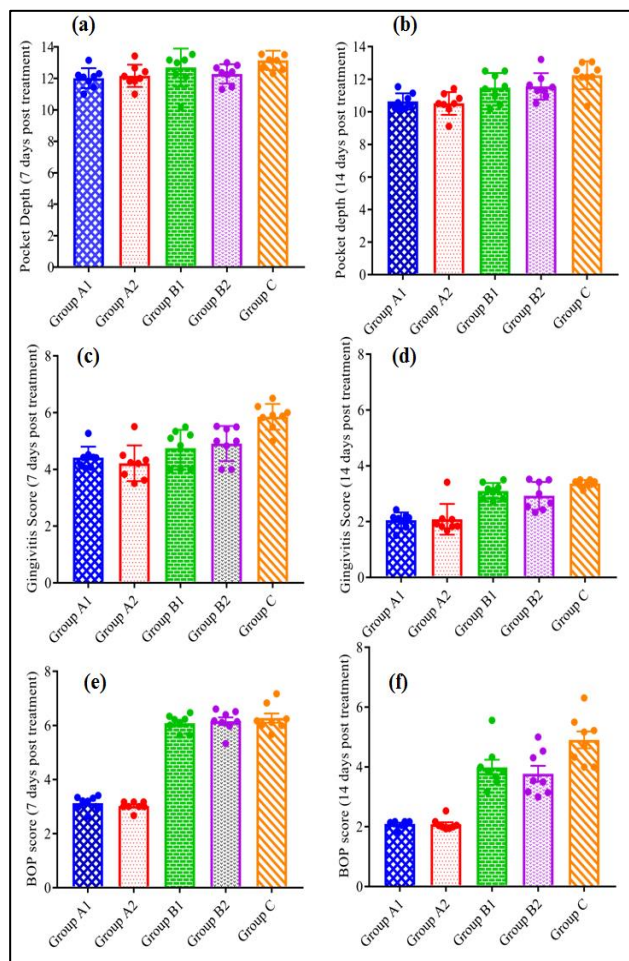


Figure 3: Results of inter group comparative study showing pocket depth (a and b), BOP score (c and d), and gingival score (e and f) in different treatment groups at 7 days post treatment and 14 days post treatment. Data presents mean \pm SEM (n = 8).

The results of microbiological study are presented in Figure 4. In case of the group A1 subjects, the mean spirochaete score was 18.62, 6.52 and 1.41, respectively at baseline, after 7 days and 14 days post treatment. A mean value of 16.34, 36.42 and 45.72 was obtained at baseline; after 7 days and 14 days, respectively, for gram + ve cocci. The mean gram + ve bacilli score was 11.33, 25.61 and 35.67, respectively, at baseline; after 7 days and 14 days of the treatment. The mean Gram -ve bacilli score were 19.12, 17.91 and 12.89, respectively, at baseline; after 7 days and 14 days of the treatment. The results suggest that the effect on therapy of gram -ve bacilli was non-significant ($p < 0.0001$) as the calculated F value was less than the table value.

In case of group A2, the mean spirochaete score was 18.15, 7.01 and 0.79, respectively, at baseline, and 7 days and 14 days of the treatment. The mean gram +ve cocci score for this group was 17.05, 36.81 and 45.92 at different study periods. The mean scores for gram +ve bacilli were 11.18, 25.71 and 36.86, respectively at baseline, 7 day and 14 day post treatment. Similarly, the mean score for gram -ve cocci were 35.13, 11.98 and 1.97, respectively. The mean scores for gram -ve bacilli were 18.15, 18.11 and 13.87, respectively, at different time intervals. In case of group B1 subjects, the mean spirochaete score were 19.11, 11.17 and 6.45, respectively, at baseline; after 7 days and 14 days of the treatment. The comparison of microbial score was carried out following Two-way ANOVA. The results showed a statistically significant ($P < 0.001$) effect of the therapy except in case of gram -ve bacilli (Table 2).

DISCUSSION

Periodontitis is the process of local inflammation triggered by bacterial insult, which lead to the destruction of periodontal tissues. It has been reported as the most prevalent microbial diseases of mankind. Periodontitis include various conditions such as aggressive periodontitis, chronic periodontitis, necrotizing periodontitis and systemic disease-associated periodontitis.

It has been reported that the periodontitis is associated with the systemic inflammatory host responses that may contribute to the higher risk for cardiovascular disease. The increased levels of C-reactive protein have been found to be a predictor of increased risk for cardiovascular disease.²⁴ Gingivitis is a common problem among different community with a high pervasiveness in all age groups. Several indices have been proposed to assess gingival inflammation. However, bleeding is the considered as most meaningful and earliest sign of inflammation.²⁵

Clindamycin, erythromycin, metronidazole, ornidazole, tinidazole, and tetracyclines are example of systemic drugs which are currently used to treat periodontal conditions. The drugs of nitroimidazole group such as metronidazole, ornidazole, satranidazole etc. are specifically anti-anaerobically directed drugs and therefore are recommended to treat the periodontitis caused by the pathogenesis of anaerobes. Therefore, in the present study we made an attempt to investigate the efforts based on clinical and microbiological aspects of satranidazole and to compare its efficacy with the most widely used drug ornidazole as an adjunct to conventional therapy.

To ensure the more reliable evaluations, before the administration of drugs, we followed a double blind format for the documentation of the disease activity. We considered only 6 teeth as advocated by Ramfjord. Paper

point technique was used to collect microbiological samples. Before sample collection, the gingival area was

made saliva free by applying cotton rolls and dried gently by compressed air.

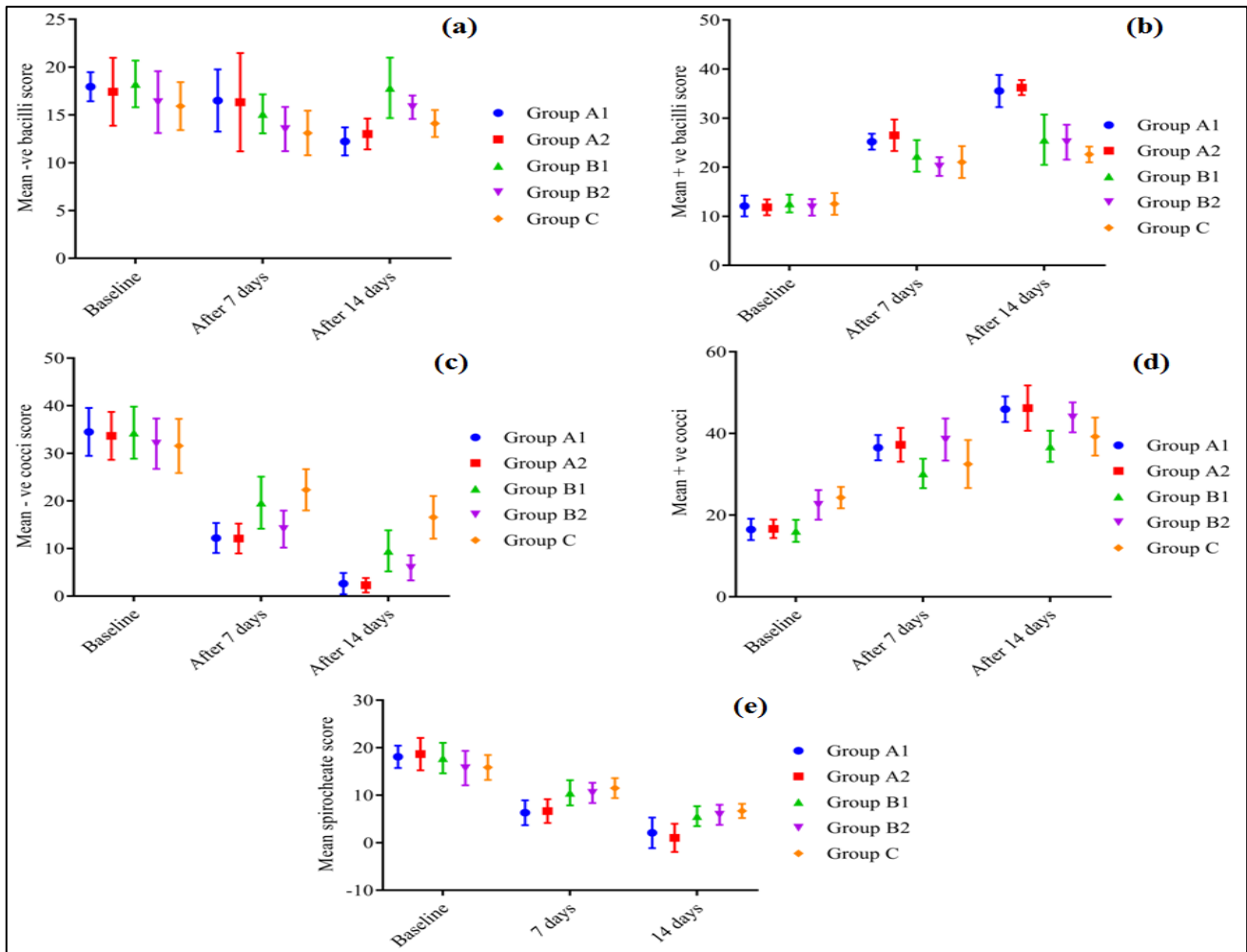


Figure 4: Results of mean gram -ve bacilli score (a) mean gram +ve bacilli score (b), mean gram -ve cocci score (c), mean gram +ve cocci score (d), and mean spirochaete score (e) in different treatment groups at baseline (before treatment), 7 days post treatment and 14 days post treatment. Data presents mean ± SEM (n = 8).

The observations revealed significant decrease in the mean gingival score from baseline to the end of the study period (day 14) in all the groups. The gingival score was significantly reduced in subjects of group A1 and A2 who received both ornidazole and satranidazole along with SRP when compared to subjects of group B1 and B2 for whom only SRP was done. Satranidazole and ornidazole were equally effective for the gingival status. SRP reduced gingival score when compared from baseline to the end of the study period. Similar results have been reported earlier.²⁶ The highest degree of decrease in pocket depth was observed in subjects received ornidazole in conjunction with SRP (group A2). However, the mean reduction in pocket depth at baseline, 7 day and 14 day post treatment were non-significant. Various investigators have also reported similar findings.²⁷⁻³⁰ Eliciting bleeding by probing approach

varies based on the index employed. Bleeding can be elicited by running a probe along the gingival margin at the sulcus level or by inserting the probe towards the bottom of the pocket.^{22,23} The intergroup comparison reveals that satranidazole or ornidazole are undoubtedly superior to the mechanical debridement alone in periodontal therapy.

No significant difference in gram -ve bacilli count was observed in subjects treated with either satranidazole or ornidazole along with SRP or in subjects only on drug regimen satranidazole or ornidazole. However, the number of gram -ve bacilli was increased on days 14 of the study in groups B and C subjects. But, when satranidazole +SRP and ornidazole +SRP groups were compared with only SRP group, spirochaete count was significantly increased. The number of Gram -ve bacilli

increased in the placebo or SRP group as compared to satranidazole or ornidazole +SRP group after 7 days post treatment. The results of microbiological investigations suggest that satranidazole and ornidazole offered beneficial effect on clinical parameters as well as on the count of spirochaete, gram -ve cocci and gram -ve bacilli over SRP alone. A complete reverse effect was recorded in case of gram +ve cocci and gram +ve bacilli with an

increase in microorganism count during the therapy. The subjects treated with drug +SRP had better results when compared to the subjects who received drug only.

This could be due to the fact that the hindrance caused by the plaque. The result shows ornidazole +SRP better than satranidazole +SRP. However, this effect was non-significant.

Table 4: Results of two way ANOVA on the data obtained from microbiological investigations.

Source of variation	Sum of square	Degree of freedom	Mean squares	Calculated F	Remark
Gram - ve Cocci (p <0.0001)					
CSS	1027	4	256.7	F (4, 105) = 1.738	
RSS	13823	2	6912	F (2, 105) = 46.78	Significant
ESS	15515	105	147.8		
Gram + ve Cocci (p <0.0001)					
CSS	714.2	4	178.5	F (4, 105) = 1.453	
RSS	11232	2	5616	F (2, 105) = 45.71	Significant
ESS	12901	105	122.9		
Gram - ve Bacill (p <0.0001)					
CSS	90.34	4	22.59	F (4, 105) = 0.3929	
RSS	157.2	2	78.62	F (2, 105) = 1.368	Non-significant
ESS	6036	105	57.49		
Gram + ve Bacill (p <0.0001)					
CSS	828.6	4	207.1	F (4, 105) = 3.535	
RSS	5824	2	2912	F (2, 105) = 49.69	Significant
ESS	6153	105	58.6		
Spirocheate (p <0.0001)					
CSS	160.2	4	40.05	F (4, 105) = 0.7024	
RSS	3430	2	1715	F (2, 105) = 30.08	Significant
ESS	5986	105	57.01		

CONCLUSION

The study was successfully carried out to examine the therapeutic efficacy of satranidazole and ornidazole over a period of 14 days. A significant improvement in the treatment of gingival inflammation, pocket depth and BOP was observed in all the groups. Both the drugs (i.e. satranidazole and ornidazole) were equally effective when used alone and with SRP in reducing spirocheates, gram -ve bacilli and gram -ve cocci. Ornidazole showed better results than satranidazole for shorter duration. At the end of study, a significant reduction in pocket depth, gingival score and BOP was observed in treated groups.

The study pointed usefulness of systemic satranidazole and ornidazole as an adjunct to the mechanical debridment. However, long term clinical trials with larger population group are recommended for the selected model drugs to confirm the superiority of one drug over the other.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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