

## Evaluation of Ornidazole Gel as an Adjunct to the Phase I Therapy

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### ABSTRACT

**Aim:** Gingivitis is a common periodontal condition affecting most of the population of the world. Beneficial results have been achieved by researchers with use of antibiotics as an adjunct to phase I therapy. This study was done to evaluate the therapeutic effectiveness of Ornidazole containing gel as an adjunct to scaling in comparison with scaling alone.

**Materials and Method:** Total 30 subjects of both the sexes diagnosed with chronic generalized gingivitis were recruited for the study. A split mouth study was conducted where scaling was done on the control site & scaling along with Ornidazole gel application was done on the test site. Modified gingival index and plaque index were recorded at baseline, 2 weeks and 4 weeks.

**Results:** This clinical study showed statistically significant improvement in gingival status of all the patients. For both the groups significant difference in mean score (0.52) of modified gingival index was observed but there was no significant difference in mean plaque score between two sites.

**Conclusion:** The result showed that scaling alone can improve the gingival status; however additional benefits can be obtained when antimicrobial gel is used as an adjunctive therapy.

**Keywords:** Antibiotics, Gingivitis, Ornidazole.

### INTRODUCTION

Dental diseases are recognized as the major public problem throughout the world. They are chronic disorders affecting most of the people during life. Periodontitis manifests as inflammation of the gingival and the deeper periodontal tissues which may result into loss of supporting structures of tooth<sup>1</sup>. The disease affects the gingiva causing gingivitis which then progresses into periodontitis.



Periodontal diseases are mostly associated with plaque induced bacterial infections<sup>2</sup>. The ultimate way to

maintain good gingival status is plaque control<sup>3</sup>. The mechanical therapy includes scaling and root planing that remove the supragingival & subgingival plaque & calculus followed by adequate maintenance which give beneficial effects in gingivitis as well as periodontitis<sup>4,5</sup>.

Along with the mechanical debridement various antimicrobial agents have been used to prevent the plaque accumulation & disease progression<sup>6</sup>. These agents can be used for rinsing, irrigation, systemic administration or local application. Success of any drug delivery system depends upon its ability to deliver antimicrobial agents in sufficient concentration to exert their

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effects. The medicament must retain at local site long enough to ensure an efficacious outcome. A hundred fold higher concentration of antimicrobial agent can be achieved by the local route of drug delivery as compared to the systemic drug administration<sup>7</sup>.

Various chemotherapeutic agents including tetracycline, minocycline, doxycycline, metronidazole, ornidazole, chlorhexidine etc. are available for local application. They come in form of gels, paste, films, strips and fibers<sup>8-12</sup>.

Nitroimidazole compound is one such agent that acts by inhibiting DNA synthesis. It works on the principle that inactive form passively diffuses into cell where it is activated by chemical reduction. The nitro group gets reduced to anion radicals which causes oxidation of DNA leading to strand breakage and cell death<sup>13</sup>. 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*, *C. Rectus* which are implicated in periodontal disease.

This present study was conducted to evaluate the efficacy of Ornidazole Gel as a local application to reduce gingival inflammation after the phase-I therapy.

## MATERIALS AND METHOD

### Study subjects and design

The study was conducted from December 2013 to February 2014. A total of 30 patients, aged between 18 to 40 years, who reported to the Department of Periodontics, Karnavati School of Dentistry and diagnosed with chronic generalized gingivitis were recruited for the study. Ethical clearance was obtained from the concerned Ethical committee of the institution with number KSD-312. All patients received a detailed description of the proposed treatment and were asked to sign informed written consent.

Inclusion Criteria was as follows: the patients diagnosed with chronic generalized gingivitis, with no history of periodontal therapy

preceding six months or previous use of antibiotics or anti-inflammatory medication within the preceding six weeks and gingival index  $\geq 1$ . Exclusion criteria was patient having any systemic disease, patients under orthodontic treatment, those having radiographic evidence of bone loss and those who had a habit of smoking or using tobacco in other forms.

### Clinical Study

The study had a split mouth study design where all patients under went phase-I therapy. Split mouth study design was selected to reduce bias. The subjects selected in present study were diagnosed as chronic generalized gingivitis and test and control sites were selected by 'coin and toss' method. Clinical parameters measured were Modified Gingival Index<sup>14</sup> and Plaque Index by Turesky et al modification of Quigley Hein Plaque index<sup>15</sup>. All the parameters were checked at the baseline, 2 weeks and at 4 weeks. On control site only scaling was performed, while on test site along with scaling local application of gel containing Ornidazole was advised. Patients were instructed to apply the gel 3 times a day and not to rinse mouth for at least half an hour.

### Statistical analysis

Data collected were uploaded to a database. Mean & SD was calculated on each side. Intra- and intergroup comparisons were conducted using the Unpaired t-test and Anova test respectively. Values of  $p < 0.05$  were regarded as statistically significant.

## RESULT

The study had mean age of 27 years. In which there were 18 males and 12 females. All the patients completed the scheduled 4 weeks examinations appointments.

### Gingival Index: (Table: 1,2)

Intergroup comparison of gingival index at different time period revealed that the mean difference in gingival index score at baseline was  $2.05 \pm 0.13$  for control sites &  $2.01 \pm 0.13$  for the test sites, which was statistically non-significant. The mean difference in gingival index score at 2 weeks was  $1.69 \pm 0.12$  for control sites &  $1.47 \pm 0.15$  for the test sites, which was statistically significant.

**Table 1:** Intragroup comparison of Modified Gingival Index.

Site	Intragroup Comparison	Mean	P Value	S or NS
Test Sites	Baseline	2.01±0.13	<0.05	S*
	2 weeks	1.47±0.15		
	Baseline	2.01±0.13	<0.05	S*
	4 weeks	0.96±0.14		
	2 weeks	1.47±0.15	<0.05	S*
	4 weeks	0.96±0.14		
Control Sites	Baseline	2.05±0.13	<0.05	S*
	2 weeks	1.69±0.12		
	Baseline	2.05±0.13	<0.05	S*
	4 weeks	1.48±0.12		
	2 weeks	1.69±0.12	<0.05	S*
	4 weeks	1.48±0.12		

\*Significant

**Table 2:** Intergroup comparison of Modified Gingival Index.

Time Period	Site	Mean±S.D.	P Value	S Or NS
Baseline	Test	2.01±0.13	0.91	NS†
	Control	2.05±0.13		
2 Weeks	Test	1.47±0.15	<0.05	S*
	Control	1.69±0.12		
4 Weeks	Test	0.96±0.14	<0.05	S*
	Control	1.48±0.12		

\*Significant, †Non-significant

**Table 3:** Plaque Index.

Time Period	T - Value	P- Value	S OR NS
Baseline	0.43	0.66	NS*
2 weeks	0.55	0.58	NS*
4 weeks	0.38	0.70	NS*

\*Non-significant

The mean difference in gingival index score at 4 weeks was 1.48±0.12 for control sites & 0.96±0.14 for the test sites which was statistically significant.

**Plaque Index: (Table: 3)**

The plaque index showed significant improvement in both test and control sites. This shows the effect of scaling and patient’s good oral hygiene maintenance. The plaque index values at baseline, 2 weeks and 4 weeks were 0.66, 0.58, 0.70 respectively.

**DISCUSSION**

In gingivitis, successful outcome of periodontal therapy depends upon the elimination of pathogenic organism found in dental plaque film associated with the tooth surface. The present study was conducted to evaluate the effect of Ornidazole gel in treatment of gingivitis. The subjects selected in present study were diagnosed as chronic generalized gingivitis and test and control sites were selected randomly.

Traditional therapy for periodontal disease include mechanical scaling and root planning (SRP), which removes the deposits from the tooth surface

and shifts the pathogenic microbiota to one compatible with periodontal health<sup>14-17</sup>. However, the pocket anatomy is a significant limiting factor in mechanical access, and sufficient reduction of the bacterial load is difficult to achieve<sup>18</sup>. An increased interest in antibiotic therapy as an adjunct to standard periodontal treatment regime began in the late 1970's with the realization that certain bacteria are frequently associated with the disease process. Thus, emerging evidence of bacterial specificity in certain types of periodontitis has led to treatment strategies, which are primarily aimed at suppression or elimination of specific periodontal pathogens. These therapeutic rationales rely heavily on systemic or local administration of antimicrobial agents. Since use of systemic antibiotics is associated with some disadvantages such as inability of systemic drugs to achieve high gingival crevicular fluid concentration,<sup>19</sup> an increased risk of adverse drug reactions,<sup>20</sup> increased selection of multiple antibiotic-resistant micro-organisms<sup>21</sup> and uncertain patient compliance<sup>22</sup>, the local administration of drugs is recommended.

Ornidazole specifically acts on gram negative anaerobic, facultative bacteria which are responsible for periodontal disease. Ornidazole requires a very low minimum inhibitory concentration to inhibit the growth of periodontal pathogens as compared to that of Metronidazole. The antimicrobial activity of Ornidazole has been proposed due to the reduction of nitro group to a more reactive amine that attacks microbial DNA, inhibiting further synthesis and causing degradation of existing DNA<sup>23-25</sup>.

This present study shows significant improvement in clinical parameters at test sites where combination treatment with antimicrobial agent along with scaling was performed.

As home care regime the use of antimicrobial agent proves as a useful mode of initial periodontal therapy and could prevent the need of a surgical phase in such patients. Further studies are needed to investigate its use in persistent periodontitis.

## CONCLUSION

Hence, it can be concluded that the topical application of Ornidazole gel after the phase-I

therapy reduces the gingival inflammation compared to phase-I therapy alone. In certain gingival inflammatory conditions where in standard scaling procedures don't give adequate results, the adjunctive use of Ornidazole gel can give desired beneficiary effect.

## CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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