Research Article

Effect of systemically administered Ornidazole and Metronidazole with or without scaling and root planing: A clinical study

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ABSTRACT

The present study evaluates and compares the clinical effects of systemic metronidazole and ornidazole in sites with or without scaling and root planing (SRP) in generalized chronic periodontitis patients in terms of gingival scores (GS), Probing depth (PD) and Bleeding on probing (BOP). A total of 40 patients suffering from chronic periodontitis (18-42 years) were selected & randomly divided equally into three groups on the basis of the treatment plan. The clinical parameters were assessed at baseline i.e. day 0, day 7 and day 14 post-treatment. Clinical parameters gingival inflammation, pocket depth and bleeding on probing over a period of 14 days Ornida zo + SRP proved to be a better mode of treatment. Significant improvement was noted in all the five treatment modalities in treating chronic generalized periodontitis.

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Introduction

Microflora associated with periodontal diseases are very complex consisting mainly of Gram negative anaerobic bacteria (Loesche et al.1985; Kamma et al. 1995, 1999; Moore and Moore 2000). It is now recognized that advance periodontitis does not always respond to conventional management now a days various types of antibiotics given systemically or locally improve the success rate of periodontal therapy (Genco 1981; Slots and Rams 1990).

Metronidazole, a nitromidazole compound was developed in France during the 1950s to treat protozoal infections. Ornidazole is also a nitroimidazole, which is used for the treatment of anaerobic infections and is comparable to or has better antibacterial properties than Metronidazole (Wust 1977). Comparative pharmacokinetic studies have shown that Ornidazole has a higher level of half-life elimination from plasma (14.4 hours) than Metronidazole (7.3 hours), therefore requiring less frequent intake (Ramfjord 1959).

This property of Ornidazole makes it a better choice than Metronidazole, when patient compliance is kept in view. Since there is paucity of literature regarding its role in the treatment of periodontal patients, therefore, the present study has been carried out the effectiveness of Ornidazole and Metronidazole with or without scaling and root planing.
Materials and methods
A short term clinical study was conducted on 40 chronic generalized periodontitis patients in age group of 18-42 years. The study was conducted in the post-graduate clinic of the department of Periodontology, Chandra Dental College & Hospital, Safedabad, Barabanki, Uttar Pradesh.

Inclusion criteria: Indian adults of both genders of age range between 18-42 years, Volunteers with diagnosed cases of mild to moderate Generalized Chronic Periodontitis with pocket depth >4mm and should be systemically healthy.

Exclusion Criteria: Smokers, tobacco and/ or pan masala chewers, alcoholics, drug addicts, Pregnant and lactating females, Persons having systemic diseases or conditions that influence the progression and/or clinical characteristics of periodontal disease. Persons having taken antibiotics and anti-inflammatory drugs within the preceding 3 months or currently taking medications, periodontal treatment within last 6 months.

The study protocol was explained to all the volunteers and those who accepted were enrolled and grouped. Patients were randomly placed into three groups on the basis of treatment executed. Group I and II were further sub-divided into two subgroups - Group I- Patients were subjected to scaling and root planing (SRP) in addition to drugs given orally. Subgroups I a- Drug A (MET+SRP) I b- Drug B (ORN+SRP) Group II- Only drugs were given orally without SRP. Subgroups II a- Drug A(MET) only II b- Drug B(ORN) only Group III or Placebo group- SRP was performed in addition to Placebo given orally Drug C + SRP . There were eight patients in each group.

Clinical Parameters
The following clinical parameters were recorded in each patient at baseline (day 0), day 7 and day 14 post treatment. According to the Ramfjord (1959) six teeth (16, 21, 24, 36, 41 and 44) were considered for clinical examination. Gingival Score was clinically assessed using gingival index (Loe 1967), while BOP by Papillary Bleeding Index. Probing pocket depth was measured by a standard probe-UNC 15 probe on each surface of the. All clinical evaluations were made by the same periodontist.

Formulation of Drug
A total of 1456 empty capsules of same size and colour were purchased from the chemist shop (672 each for Metronidazole, 448 each for Ornidaole and 336 for Placebo). Metronidazole tablet (400 mg) and 500 mg of Ornidaole tablet were grounded into fine powder form and then filled into each capsule. Total 336 capsules were filled with glucose which served as Placebo. These capsules were placed in three containers which were randomly labelled A, B and C by a third person.

Treatment Procedure
Baseline recordings of clinical parameters were taken and patients subjected to various treatments. Patients were instructed to orally take the drug, Drug A thrice a day at 8 hour interval and Drug B twice a day at 12 hour interval.

Results
I. Gingivitis score
For each group, comparing the mean difference in gingivitis score between the periods (Table 2), Tukey test showed significant (p<0.001) decrease in gingivitis score at both post periods (day 7 and day 14) as compared to pre-treatment (day 0) in all groups. Further, in all groups, the mean gingivitis score also decrease significantly (p<0.05 or p<0.01 or p<0.001) at day 14 as compared to day 7.

II. Probing Depth
Comparing the mean difference in probing depth between the groups (Table 3), Tukey test showed similar (p>0.05) probing depth between the groups at day 0 indicating it comparable. Further, it also remain similar (p>0.05) between the groups at day 7 i.e. did not differ significantly. In contrast, at day 14, the mean probing depth lowered significantly (p<0.05 or p<0.001) in
Group Ib as compared to both Group IIa and Group IIb. Further, at day 14, it also lowered significantly (p<0.01) in Group III as compared to Group IIb.

### III. Bleeding on Probing
Comparing the mean difference in bleeding on probing between the groups (Table 4), Tukey test showed similar (p>0.05) bleeding on probing between the groups at day 0 indicating it comparable. In contrast, at both day 7 and day 14, it lowered significantly (p<0.05 or p<0.001) in Group Ib as compared to Group IIa, Group IIb and Group III. Further, at day 14, it also lowered significantly (p<0.05) in Group Ia as compared to Group III.

**Table 1:** Allocation of group and distribution of patients.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Group name</th>
<th>No of patients (n=40) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metronidazole +SRP</td>
<td>Group Ia</td>
<td>8 (20.0)</td>
</tr>
<tr>
<td>Ornidazole +SRP</td>
<td>Group Ib</td>
<td>8 (20.0)</td>
</tr>
<tr>
<td>Metronidazole alone</td>
<td>Group IIa</td>
<td>8 (20.0)</td>
</tr>
<tr>
<td>Ornidazole alone</td>
<td>Group IIb</td>
<td>8 (20.0)</td>
</tr>
<tr>
<td>Placebo + SRP</td>
<td>Group III</td>
<td>8 (20.0)</td>
</tr>
</tbody>
</table>

**Table 2:** Pre and post gingivitis score (Mean ± SD) of five groups over the periods.

<table>
<thead>
<tr>
<th>Group</th>
<th>Day 0 (n=8)</th>
<th>Day 7 (n=8)</th>
<th>% change (day 0 to day 7)</th>
<th>Day 14 (n=8)</th>
<th>% change (day 0 to day 14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group Ia</td>
<td>2.72 ± 0.15</td>
<td>0.67 ± 0.08</td>
<td>75.36</td>
<td>0.38 ± 0.07</td>
<td>86.0</td>
</tr>
<tr>
<td>Group Ib</td>
<td>2.64 ± 0.18</td>
<td>0.62 ± 0.14</td>
<td>76.51</td>
<td>0.33 ± 0.05</td>
<td>87.5</td>
</tr>
<tr>
<td>Group IIa</td>
<td>2.76 ± 0.15</td>
<td>2.00 ± 0.21</td>
<td>27.53</td>
<td>1.13 ± 0.13</td>
<td>59.2</td>
</tr>
<tr>
<td>Group IIb</td>
<td>2.57 ± 0.18</td>
<td>2.08 ± 0.23</td>
<td>19.06</td>
<td>1.52 ± 0.28</td>
<td>40.9</td>
</tr>
<tr>
<td>Group III</td>
<td>2.66 ± 0.19</td>
<td>0.76 ± 0.15</td>
<td>71.42</td>
<td>0.43 ± 0.17</td>
<td>83.9</td>
</tr>
</tbody>
</table>

**Table 3:** Pre and post probing depth score (Mean ± SD) of five groups over the periods.

<table>
<thead>
<tr>
<th>Group</th>
<th>Day 0 (n=8)</th>
<th>Day 7 (n=8)</th>
<th>% change (day 0 to day 7)</th>
<th>Day 14 (n=8)</th>
<th>% change (day 0 to day 14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group Ia</td>
<td>6.63 ± 0.44</td>
<td>5.75 ± 0.53</td>
<td>13.3</td>
<td>4.19 ± 0.37</td>
<td>36.8</td>
</tr>
<tr>
<td>Group Ib</td>
<td>6.56 ± 0.50</td>
<td>5.44 ± 0.62</td>
<td>17.1</td>
<td>3.44 ± 0.82</td>
<td>47.6</td>
</tr>
<tr>
<td>Group IIa</td>
<td>6.31 ± 0.65</td>
<td>5.63 ± 0.74</td>
<td>10.8</td>
<td>4.63 ± 0.58</td>
<td>26.7</td>
</tr>
<tr>
<td>Group IIb</td>
<td>6.38 ± 0.64</td>
<td>5.81 ± 0.70</td>
<td>8.9</td>
<td>5.25 ± 0.85</td>
<td>17.6</td>
</tr>
<tr>
<td>Group III</td>
<td>6.50 ± 0.53</td>
<td>5.13 ± 0.79</td>
<td>21.1</td>
<td>3.88 ± 0.64</td>
<td>40.4</td>
</tr>
</tbody>
</table>

**Table 4:** Pre and post bleeding on probing (Mean ± SD) of five groups over the periods.

<table>
<thead>
<tr>
<th>Group</th>
<th>Day 0 (n=8)</th>
<th>Day 7 (n=8)</th>
<th>% change (day 0 to day 7)</th>
<th>Day 14 (n=8)</th>
<th>% change (day 0 to day 14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group Ia</td>
<td>4.50 ± 0.53</td>
<td>3.25 ± 0.46</td>
<td>21.8</td>
<td>1.75 ± 0.71</td>
<td>61.1</td>
</tr>
<tr>
<td>Group Ib</td>
<td>4.63 ± 0.52</td>
<td>2.25 ± 0.46</td>
<td>51.4</td>
<td>0.38 ± 0.52</td>
<td>91.9</td>
</tr>
<tr>
<td>Group IIa</td>
<td>4.63 ± 0.52</td>
<td>4.25 ± 0.46</td>
<td>8.2</td>
<td>2.38 ± 0.52</td>
<td>48.6</td>
</tr>
<tr>
<td>Group IIb</td>
<td>4.63 ± 0.52</td>
<td>3.50 ± 0.76</td>
<td>24.4</td>
<td>2.75 ± 0.89</td>
<td>40.5</td>
</tr>
<tr>
<td>Group III</td>
<td>4.63 ± 0.52</td>
<td>4.13 ± 0.83</td>
<td>10.8</td>
<td>3.00 ± 0.76</td>
<td>35.1</td>
</tr>
</tbody>
</table>
Discussion

The drugs so far used to treat periodontal disease include Tetracycline, Clindamycin, Erythromycin, Metronidazole, Tinidazole, Ornidazole and Others. The Group Nitroimidazole (Metronidazole, Ornidazole etc.) is specifically antianaerobically directed and is therefore indicated as anaerobes are implicated in the pathogenesis of periodontitis (Muhlemann 1977; Watts et al. 1986). But the role of Ornidazole is not well documented. Therefore in the present study efforts were made to evaluate clinical and microbiological aspects of Ornidazole and to compare efficacy with most widely used drug Metronidazole as an adjunct to conventional mechanical therapy. The most frequently reported dosage in dentistry for Metronidazole is 800 mg daily for 7 days. Britt & Pohald (1986) & Von Oosten MA et al. (1986) reported that single dose of 750 mg exceeds the minimal inhibitory concentration for most anaerobic microorganisms. Schwartz and Jennet (1976) stated that Ornidazole a closely related analogue of Metronidazole has wider antibacterial spectrum and higher serum half-life. It has a fewer frequency of side effects only in higher dose of 1.5 to 2.0 mg. To make evaluations more reliable a double blind format was used and documentation of disease activity was done before the administration of drugs.

Gingival score was significantly reduced in subjects receiving both Metronidazole and Ornidazole along with SRP (group Ia & Ib) as compared to subjects in whom only SRP was done. Effect of both metronidazole and ornidazole on the gingival status was nearly same as seen in table 2, where reduction in gingivitis score between group Ia and Ib; and again between group IIa and IIb was insignificant at both time periods. The connotation that inflammation decreases after SRP has also been observed by Lavanchy et al (1987). But the extent of reduction in gingivitis score was significantly less when compared to Metronidazole/Ornidazole + SRP group. These results are also in conformity with that of Gusberti et al (1988), Jenkins et al (1989) and Soder et al (1984) who found that systemic Metronidazole either alone or in combination with debridement produced a modest clinical improvement after debridement alone has failed.

Although the mean reduction in pocket depth at different time intervals in all groups was significant (Table 3) but pocket depth was maximally decreased (47.60%) in subjects whom the drug Ornidazole was given in conjunction with SRP and pocket depth was decreased (36.80%) in subjects whom the drug Metronidazole. This finding is conformity with that of Bardesten et al (1984) and Loesche et al (1991) had also stated that pocket depth decreased after supragingival and sub-gingival scaling. Again pocket depth was more reduced (10.80%) in subjects taking Ornidazole as compared to Metronidazole. On intergroup comparison. The results are also in conformity to Giedrys-Leeper et al (1985), Watts et al (1986) and Joyston-Bachal et al (1986) who demonstrated a statistically significant improvement in mean pocket depth of pockets achieved with use of Metronidazole in the severe group.

Reduction in mean BOP at different time periods in all group were significant, but on inter group comparison of these data (Table 4) showed that reduction of BOP in group Ia and Ib were non-significant although the mean of Ib was less. On comparison of group IIa and IIb after 7 days showed less significant results indicating that IIb is better as mean is less but after 14 days this showed non-significant result. These results are similar to Tinoco et al (1998), Lundstorm et al (1984) who observed the effect of combined systemic antibiotic therapy & mechanical debridement in patients with recurrent periodontitis. The inter group comparison reveals that Ornidazole or Metronidazole as an adjunct to mechanical debridement is undoubtedly superior to mechanical debridement alone. But there is no significant difference between Ornidazole and Metronidazole in improving clinical condition.

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Conclusion

Significant improvement was noted in all the five treatment modalities in treating gingival inflammation, pocket depth and bleeding on probing over a period of 14 days. The findings concluded that in the treatment of gingival inflammation Ornidazole + SRP proved to be a better mode of treatment.

Conflict of interest

Authors declare no conflict of interest.

References


