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Research Article

EVALUATION OF ORNIDAZOLE GEL AS AN ADJUNCT TO NON SURGICAL PERIODONTAL THERAPY IN CHRONIC PERIODONTITIS PATIENTS

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A B S T R A C T

Aim: To evaluate the efficacy of local application of Ornidazole Gel as adjunct to the phase-I therapy.
Materials and methods: Total 30 subjects of both the sexes diagnosed with chronic generalized periodontitis 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. 'p'laque index , pocket depth and relative attachment level were recorded at baseline and 1 month. Results: This clinical study showed statistically significant improvement in periodontal status of all the patients. Test (ornidazole) sites showed a significant decrease in pocket depth, plaque index and attachment loss when compared to the control sites.
Conclusion: The result showed that scaling alone can improve the periodontal status; however additional benefits can be obtained when antimicrobial gel is used as an adjunctive therapy.

INTRODUCTION

Periodontal disease is as an infectious disease involving both inflammatory and immune responses, leading to increased pocket depth, attachment loss and/or destruction of alveolar bone and cementum.[1] Treatment modalities to resolve periodontal inflammation can be surgical or nonsurgical periodontal therapy based on the severity of periodontal destruction. Nonsurgical therapy includes both mechanical and chemotherapeutic methods to minimize or eliminate microbial biofilm which is the prime etiological factor of gingivitis and periodontitis. Systemic use of antibiotics can interfere with normal body systems and may cause several side effects. Local administration of antibiotics or antimicrobials appears to be an effective means of eliminating these adverse reactions.[2] The concept of controlled-release local delivery of therapeutic agents, either antimicrobials or anti-inflammatory agents, was championed and developed into a viable concept primarily by Dr. Max Goodson. Goodson's first delivery devices[3,4] involved hollow fibers of cellulose acetate filled with tetracycline. Localized antimicrobial therapy has aroused considerable interest because of the site-specific nature of periodontal infections; the higher concentration of antimicrobial agent subgingivally, lesser the side effects of systemic antibiotic use. Main advantages of local drug delivery include minimum systemic involvement, better patient compliance, and minimum discomfort. Local drug delivery releases the antimicrobial agent for an extended period at a steady pharmacological level. Among the antimicrobial agents, metronidazole, ornidazole, doxycycline, minocycline, chlorhexidine, stannous fluoride, and others have been applied subgingivally in gel forms or other sustained□release local delivery systems as varnishes, chips, or fibers.[5] Metronidazole is the most common broad□spectrum antibiotic and is active against most of the periodontal pathogens. Nitroimidazole compound 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 into anion radicals which causes oxidation of DNA leading to strand breakage and cell death.[6] Hence, it has both antimicrobial and mutagenic effects. This effect is primarily seen on obligate Gram negative anaerobes such as *Porphyromonas gingivalis*, *Prevotella intermedia*, *Fusobacterium*, *Selenomonas sputigina*, *Bacteroides forsythus,* and the Gram positive anaerobes such as *Peptostreptococcus* and *Campylobacter rectus*, which are implicated in periodontal disease.[6] This present study was conducted to evaluate the efficacy of local application of Ornidazole Gel as adjunct to the phase-I therapy.

MATERIALS AND METHODS

Split mouth study was conducted compromising of 30 patients (14 males and 16 females) aged 28–52 years diagnosed with chronic periodontitis. A total of 30 sites among the enrolled participants were selected for the study. Inclusion criteria involves patients with atleast 20 teeth with pocket depth of 4mm to 6mm at more than 30% sites and the subjects who have not received periodontal treatment for past 6 months.

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Exclusion criteria include Patients on antibiotic therapy from the past 1 month**,** Pregnant or lactating women and smokers. Split mouth study design was selected to reduce bias and test and control sites were selected by 'coin and toss' method. On control site only scaling was performed, while on test site along with scaling single intrasulcular applications of commercially available ornidazole gel (1.0% ornidazole gel, chlorhexidine gluconate solution – 0.25% as preservative (Ornigreat, Mankind Pharma Limited, New Delhi, India) was carried out after informed consent of all the participants of the study was obtained.

Non Surgical Periodontal Therapy: Before starting the trial, all the patients were given oral hygiene instructions and underwent full mouth supra and subgingival scaling and root planing.

Clinical Measurements

Clinical parameters recorded during the course of the study were Plaque Index (PI),[7] pocket depth (PD)[8] and relative attachment level (RAL).[8] Customized acrylic stents were made for the test sites where the drug was to be placed for the standardization of the clinical parameters. All the parameters were measured at the baseline and at the end of 1 month.

Application of Gel

Subgingival delivery was performed with a 2 ml disposable syringe with a blunt needle bent at its shank by 130° and procedure continued until the pocket was completely filled. Care was taken to apply the gel without traumatizing or damaging the periodontal tissues. After insertion of the local drug delivery system, the region was secured with a periodontal pack, and the patients were advised not to eat hard food that could traumatize the gingiva. They were also advised to avoid brushing of the treated areas for 12 h and floss or use interproximal cleaning devices for 10 days. They were instructed not to use any mouthwash during the study. Patients were called for the removal of periodontal dressing on 7th day. Healing was uneventful.

Statistical analysis

The data obtained was tabulated and analyzed statistically. The intragroup comparisons were made using paired *t*-test, and intergroup comparison was done with unpaired Student's *t*-test using IBM SPSS software. A p-value of less than 0.05 was considered statistically significant.

RESULTS

All the clinical parameters were evaluated at baseline and 1 month after the nonsurgical periodontal therapy. Table 1 shows intragroup comparison of control sites at baseline and 1 month using paired *t*□test. There was a significant ($P < 0.001$) decrease in PI, PD and Relative attachment level.

Table 1 Control sites at baseline and 1 month

Parameters	At baseline	At 1 month	T value	P value
PI	2.11±.39625	1.3±.27054	6.345	.000018
PD	5.133±.833	3.2±.67612	5.8	.000042
RAL	10.13±.8338	8.133±.74322	11.83	.0001

Table 2 shows intragroup comparison of test(ornidazole) sites at baseline and 1 month using paired *t*□test. There was a significant ($P < 0.001$) decrease in PI, PD and Relative attachment level.

Table 2 Test (ornidazole) sites at baseline and 1 month

Parameters	At baseline	At 1 month	T value	P value
PI	1.98±.49051	.8460±.2643	12.75	<.001
PD	5.066±.883	2.466±.6399	8.5	<.001
RAL	10.066±.88372	7.6±.73678	12.8	<.001

Table 3 shows the intergroup comparision of control and test sites at the end of 1month using unpaired Student's *t*-test. From the table it is evident that there is statistically significant improvement in the clinical parameters at test (ornidazole) sites compared to control sites.

Table 3 comparison of control and test sites at 1 month

Parameters	Control sites	Test sites	P value
PI	1.3±.27054	.8460±.2643	.00005
PD	3.2±.67612	2.466±.6399	.005
RAL	8.133±.74322	7.6±.73678	.05

DISCUSSION

Periodontitis is a chronic inflammatory disease caused by interplay between the subgingival microbiota and the host tissue response which leads to the destruction of supporting structures of teeth. Traditional therapy for periodontal disease include mechanical scaling and root planning (SRP),which removes the deposits from the tooth surface. However, mechanical therapy may fail to eliminate the pathogenic bacteria completely because of their location within the gingival tissues or in areas inaccessible to periodontal instrumentation. The concept of locally delivering chemotherapeutic agents to the periodontal pocket as a method to treat periodontal disease has been studied for over few decades. Local drug delivery systems used as an adjunct to nonsurgical therapy has drastically improved the periodontal tissue condition. Advances in this field have led to the discovery of various new pharmacological agents to be used as local drug delivery systems. Present study was performed to assess the clinical healing following single intrasulcular applications of commercially available ornidazole gel as an adjunct to SRP. Ornidazole specifically acts on Gram-negative anaerobic and facultative bacteria which are responsible for periodontal disease. When compared to metronidazole, ornidazole requires a very low minimum inhibitory concentration to inhibit the growth of periodontal pathogens. 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.[11] This present study shows significant improvement in clinical parameters at test sites where combination treatment with antimicrobial agent along with scaling was performed. The results were in accordance with a previous study.[9] However one of the main drawbacks of this study is that microbial evaluation was not carried out and further studies should be done to wards clinical evaluation and determination of long-term efficacy of intrapocket application of ornidazole on clinical parameters with larger sample and longer follow-up periods.

CONCLUSION

It can be concluded that the topical application of Ornidazole gel as an adjunct to the phase-I therapy may prove beneficial in the treatment of periodontal diseases compared to phase-I therapy alone. However, a study on a large scale would prove conclusive.

Conflicts of Interest: None

Source of Support: Nil

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