Original Article

Effect of tetracycline HCl in the treatment of chronic periodontitis – A clinical study

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Abstract

Objective: This study was aimed to evaluate the efficacy of the adjunctive use of tetracycline fibers (Periodontal Plus AB®) as a local drug delivery with scaling and root planing, as compared with the results of one episode of scaling and root planing for the treatment of chronic periodontitis. **Materials and Methods:** The effectiveness of Periodontal Plus AB (tetracycline fiber) was assessed in 100 patients suffering from chronic periodontitis using split-mouth technique. **Statistical Analysis:** The relative efficacy of the two treatment modalities was evaluated using the paired Student's *t*-test, and the comparative evaluation between the two groups was done using the independent Student's *t*-test. **Results:** Significant improvement was found in all the variables, including reduction in pocket depth and gain in clinical attachment level, in both test and control groups in 3 months, which was statistically significant. Mean reduction in pocket depth and gain in clinical attachment level were more in test than in control group. **Conclusion:** Tetracycline fiber therapy along with scaling and root planing improves the healing outcome, namely, reduction in pocket depth and gain in clinical attachment level, when compared to scaling and root planing alone.

Key words: *Periodontal pocket, periodontitis, tetracycline*

INTRODUCTION

Periodontitis is an inflammatory disease of the periodontium caused by an ill-defined series of microbial infections which may be composed of more than 300 species of bacteria currently recognized in the oral cavity.[1]

A distinct difference exists between the composition of supragingival and subgingival plaque. Supragingival plaque exhibits accumulation of predominantly gram-positive coccoid cells, whereas periodontal pathogens in subgingival plaque are characterized by flora dominated by gram-negative anaerobic organisms.[2]

Periodontal tissue destruction can be either through direct action of bacteria on the tissue causing degradation of host tissues or those causing the release of biologic mediators in the form of enzymes and chemical mediators from the host tissue cells that lead to host tissue destruction. An important class of molecules in tissue destruction is the variety of enzymes produced by periodontal microorganisms. These enzymes appear to be capable of degrading essentially all host tissue and intercellular matrix molecules.[2,3]

Successful periodontal therapy is dependent on anti-infective procedures aimed at eliminating pathogenic organisms found in dental plaque associated with the tooth surface and within other niches in the oral cavity. Systemically administered antibacterial agents achieve relatively low concentration in pocket even at high dosage to the patient. By placing an antibiotic or antiseptic

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in direct contact with the root surface, pathogenic organisms that could not be eliminated mechanically or by power-driven instruments can be reduced or eliminated.[4,5]

The development of sophisticated subgingivally placed controlled delivery systems has provided the possibility of maintaining effective intrapocket levels of antibacterial agents for extended period of time, which has shown to alter the subgingival flora and influence the healing of the attachment apparatus.[6,7]

Tetracyclines are unique in that they are the only class of antibiotics tested to date that achieve gingival fluid levels higher than the blood levels, which is 2-4 times more than the blood levels.[8,9] Tetracyclines may increase the re-attachment or regeneration by enhancing fibroblast attachment and spreading and conditioning of root surfaces, and also inhibit collagenase activity.[10]

The purpose of this study was to compare the effectiveness of Periodontal Plus AB® (tetracycline fiber) as a local drug delivery along with scaling and root planing with that of scaling and root planing alone for the treatment of chronic periodontitis.

MATERIALS AND METHODS

Source of data

The study consists of 100 patients belonging to both sexes with age ranging from 30 to 55 years. The treatment sites were divided into two groups by split-mouth technique in each patient. Group A represents the test group where the periodontal pockets were treated with scaling and root planing, along with tetracycline filled in collagen type I fibers (Periodontal Plus AB; Advanced Biotech Products, Chennai, India). Group B represents the control group in which the subjects were treated with scaling and root planing alone.

Criteria for patient selection

Inclusion criteria

- 100 patients in the age group 30–55 years with chronic generalized periodontitis and having a probing pocket depth ≥5 mm
- Patient free from systemic illness.

Exclusion criteria

- Pregnant and nursing patients
- Allergic to tetracycline
- Received antibiotic treatment 2 weeks prior to study
- History or clinical signs of candidiasis
- Inability to comply with the follow-up visit requirements
- Smokers.

Clinical trial design

The nature and design of the clinical trial was explained to the patients and consent obtained for their participation.

The present study had split-mouth design. The patients selected had at least two or more sites with a pocket depth of ≥5 mm or more in one quadrant, excluding the third molars that required periodontal treatment. Sites should have probing depths of 5 mm or more at baseline as measured with University of North Carolina (UNC-15) graduated pocket measuring probe using customized occlusal stent.

The split-mouth study sites were randomly assigned to one of the two treatments, viz. test (scaling and root planing plus tetracycline filled type I collagen fiber application with oral hygiene instructions) and control (scaling and root planing alone).

The selected patients received full mouth scaling and root planing. A 20 min schedule was allotted to perform scaling and root planing for each of the experimental and control sites, using piezo-scales and Gracey area-specific curettes with number 1-14 for root planing. For sites receiving fiber therapy, type I collagen fibers containing 2 mg of tetracycline hydrochloride were placed in the periodontal pocket surrounding the tooth on the same day after scaling and root planning. Fibers were placed until the pocket was entirely filled to the gingival margin. On an average, 15 cm fiber was used per tooth. Periodontal pack was placed along with the gingival margin taking care not to dislodge the fiber.

Patients were instructed to avoid brushing the fiber-treated teeth and eating crusty foods for 10 days. At the fourth postoperative day following treatment, the patients were checked for fiber retention and any adverse reactions. The periodontal packs were removed 10 days following initial placement.

Clinical parameters of the selected sites were undertaken for each experimental site and control site at 0 day, 15 days, 45th day, and 90th day follow-up.

Clinical parameters

- Gingival index (Loe and Silness, 1963)
- Sulcus bleeding index (Mulhemann, 1958)

- Clinical attachment level (CAL)
- Probing pocket depth.

Data analysis

Observational data were analyzed with the Student's *t*-test. Mean values and standard deviations were calculated for each variable and examination interval. The paired Student's *t*-test was used to evaluate and establish differences between baseline and post-treatment measurements within a group. The unpaired Student's *t*-test was used to evaluate and establish differences between the test and control groups at baseline, 15 days, 45 days, and 90 days.

RESULTS

All 100 patients enrolled in this study reported for scheduled post-treatment evaluation visits.

Gingival index

No statistically significant difference in the mean values of the gingival index was found between the test and control groups at baseline ($P = 0.772$), but a significant difference was observed at 15 days ($P = 0.003$), 45 days ($P = 0.000$), and at 90 days ($P = 0.000$) [Table 1].

Bleeding index

No statistically significant difference in the mean values of the gingival index was found between the test and control groups at baseline ($P = 0.811$), but a highly significant difference was observed at 15 days ($P = 0.006$), 45 days ($P = 0.000$), and at 90 days ($P = 0.000$) [Table 2].

Probing pocket depth

No statistically significant difference in the mean values of pocket depth was found between the test and control groups at baseline ($P = 0.288$). However, the mean value at 15 days ($P = 0.018$) was significant, and the values at 45 days ($P < 0.000$) and 90 days ($P < 0.000$) were highly significant [Table 3].

Clinical attachment level

The difference in the mean values of CAL at baseline ($P = 0.530$) between the test and control groups was not significant. However, the mean values of CAL at 15 days ($P = 0.028$) was statistically significant, while the values at 45 days ($P = 0.000$) and 90 days ($P < 0.000$) were statistically highly significant [Table 4].

DISCUSSION

The prevalence and severity of periodontal disease can be reduced by both total plaque control and by selective removal or inhibition of pathogenic microflora using either systemic or locally applied antibacterial agents. Treatment of periodontitis principally attempts to slow the disease progression, prevents the recurrence of the disease, and

Table 1: Mean gingival index before and after treatment

Gingival index	Experiment group		Control group		*P*
	Mean±SD	% change from baseline	Mean±SD	% change from baseline	
Baseline	1.311±0.499	-	1.268±0.427	-	0.772
15 days	0.505±0.357	56.1	0.882±0.389	28.1	0.003
45 days	0.248±0.146	73.3	0.643±0.342	60.5	0.000
90 days	0.198±0.144	82.1	0.575±0.21	53.5	0.000
P value	<0.00**		<0.00**		-

*Paired t-test, *Significant, **highly significant, SD = Standard deviation*

Table 2: Mean bleeding index before and after treatment

Bleeding index	Experiment group		Control group		*P*
	Mean±SD	% change from baseline	Mean±SD	% change from baseline	
Baseline	1.542±0.384	-	1.575±0.515	-	0.811
15 days	0.720±0.25	53.4	1.103±0.401	34.3	0.006
45 days	0.368±0.103	76.1	0.709±0.304	50.5	0.000
90 days	0.191±0.162	87.6	0.644±0.232	60.6	0.000
P value	<0.00**		<0.00**		-

*Paired t-test, *Significant, **highly significant, SD = Standard deviation*

Table 3: Mean probing pocket depth before and after treatment

Probing pocket depth	Experiment group		Control group		*P*
	Mean±SD	% change from baseline	Mean±SD	% change from baseline	
Baseline	5.803±0.646	-	5.606±0.514	-	0.288
15 days	4.656±0.643	17.4	5.38±0.69	5.6	0.018
45 days	4.163±0.761	28.3	5.135±0.644	10	0.000
90 days	3.424±0.794	40.0	4.435±0.746	20.2	0.000
P value	<0.00**		<0.00**		-

*Paired t-test, *Significant, **highly significant, SD = Standard deviation*

Table 4: Mean clinical attachment level before and after treatment

Clinical attachment level	Experiment group		Control group		*P*
	Mean±SD	% change from baseline	Mean±SD	% change from baseline	
Baseline	3.673±1.625	-	3.553±0.562	-	0.530
15 days	2.808±0.611	24.5	3.36±0.69	9.9	0.028
45 days	2.223±0.711	41.2	3.135±0.634	15.9	0.000
90 days	1.445±0.647	61.1	2.535±0.648	29.7	0.000
P value	<0.00**		<0.00**		-

*Paired t-test, *Significant, **highly significant, SD = Standard deviation*

aims at regenerating or repairing the tissue that has been lost or damaged. Conventional treatment methods include mechanical removal of bacterial plaque (by scaling and root planing) to eliminate or reduce the number of periodontal pathogens. However, the microbiologic effects of scaling and root planing rarely result in complete removal of periodontal pathogens and appear to be some what self-limiting because bacterial pathogens may recolonize after treatment. This led to the adjunctive use of antibacterial agents either in the form of systemic or local application to overcome the efficacy of the conventional treatment.[11] There is increasing interest in the use of a reservoir of a locally delivered antibiotic in treating periodontitis. These can attain 100-fold higher concentrations of medication with significantly decreased systemic interaction as compared to systemic administration.[12] The limited use of irrigation device which gets readily washed away led to the development of sophisticated subgingivally placed controlled delivery system.[4]

Tetracycline has been incorporated into the controlled release polymer for subgingival administration in treatment of chronic periodontitis. Periodontal Plus AB is one such product that has been evaluated in this study and contains tetracycline HCl 2 mg incorporated into resorbable type I collagen fibers.

The major advantage of this product includes efficacy, ease of placement, retention after placement, ability to resorb under periodontal pocket conditions, minimal number of side effects and adverse events, and the bioactive type I collagen through which it is delivered promotes tissue regeneration into the pockets through possible cell signal transduction. Pharmacokinetic studies of Periodontal Plus AB indicate that tetracycline is released at bacteriostatic levels for at least 10 days after administration. After application, each site shows an average gingival fluid concentration of 1546 ± 125 mcg/ml tetracycline during the first 10-day treatment period.

The gingival index and bleeding index in the experimental period, i.e. on days 0, 15, 45, and 90, were compared in both the experiment and control sites. Results showed a highly significant change with regard to improvement in the gingival inflammation and reduced bleeding on probing from the baseline in both the control and experimental sites, but the reduction was more in the experimental site. The definite reduction shown could be due to regular follow-up visit, reduction in pocket depth, and reinforcement of oral hygiene instruction followed by the patient throughout the study period. These results could be correlated with similar findings observed in various other studies.[4,6,11,13-15]

Gain in CALs and reduction in probing depth are the most common parameters used to measure clinical improvement. Decrease in probing depth in the experimental site between baseline and 90 days was 41.2%, as compared to the control group which showed a decrease of 20.5%. Statistically significant reduction in the probing pocket depth was observed in both experimental and control groups. However, the experimental group demonstrated higher reduction of the probing depth compared to the control group at 90 days interval.

Our study demonstrated a statistically significant increased gain in the attachment levels in both experimental and control groups. This gain in clinical attachment from baseline to 90 days was 62.1% for the experimental group and 29.7% for the control group, indicating that the gain in CAL in the experimental group was more than in the control group.

The reduction in gingival inflammation, gingival bleeding, and probing pocket depth could be attributed to tetracycline being affective against a number of gram-positive and gram-negative cocci and bacilli, both aerobic and anaerobic, found in the oral cavity.[6,16,17]

In the controlled drug delivery system, local concentration can be achieved much higher than the systemic route. The fiber which is placed into the periodontal pocket can produce a local drug concentration 100 times higher than achievable systemically.

So, from this clinical study, it can be suggested that controlled local drug delivery system using Periodontal Plus AB (tetracycline fiber) is a simple, rapid, and non-invasive procedure. So, this can be a good treatment modality to reduce probing pocket depth, along with providing more favorable clinical attachment gain in chronic generalized periodontitis.

From the observations of this study, the following conclusions were made. Tetracycline filled type I collagen fiber (Periodontal Plus AB) therapy enhances the benefits of scaling and root planing which provide adequate therapeutic levels as a beneficial adjunctive treatment modality to enhance periodontal health, namely reduction in probing pocket depth, gain in clinical attachment level as compared to scaling and root planing only. As evident from this study, it can be assumed that tetracycline fiber therapy along with scaling and root planing is more effective than scaling and root planing alone. However, further long-term studies should be undertaken to obtain more clinical evidence for regular use of this material on clinical parameters for a larger sample.

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