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COMPARATIVE EFFICACY OF 1% ALENDRONATE GEL AND TETRACYCLINE FIBERS AS AN ADJUNCT TO SCALING AND ROOT PLANING: A RANDOMIZED CONTROL CLINICAL TRIAL

Anjali Goel *, Sachit Anand Arora and Shivjot Chhina

Department of Periodontics, I.T.S Dental College Hospital and Research Centre, Greater Noida, Uttar Pradesh, India.

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Correspondence to Author:
Anjali Goel

Department of Periodontics, I.T.S Dental College Hospital and Research Centre, Greater Noida, Uttar Pradesh, India. Pincode – 201308.

Email: dranjali01.goel@gmail.com

ABSTRACT: The objective of this study was to compare efficacy of 1% Alendronate gel and Tetracycline fibers as an adjunct to scaling and root planning (SRP). A total of 30 patients with diagnosis of chronic periodontitis (60 localized periodontitis sites) in an age group of 20-55 years were selected. None of these patients had received any non-surgical or surgical periodontal therapy and had periodontal pockets measuring 4–7 mm clinically. Two sites in any quadrants after randomization were selected in each patient. Navy Plaque index (Grossaman and Fedi) and Gingival bleeding index (GI) (Loe and Sillness), Clinical probing depth (PD) and Clinical attachment level (CAL) were measured at baseline 1,3 and 6 months. Random allocation of test site (treated with 1% Alendronate Gel) and control site (treated with Tetracycline fibers). The results revealed that there was significant improvement in all clinical parameters from baseline to 6 months and test group presented with better results than control group however the difference was not statistically significant.

INTRODUCTION: Periodontol disease is an inflammatory disease of the supporting tissues of teeth caused by an array of microorganisms, resulting in progressive destruction of periodontol ligament and alveolar bone with pocket formation, recession or both. [1] The host defense system aggravates production of cytokines and other mediators which progresses towards alveolar bone resorption and irreversible bone loss. [2-5]

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Tetracycline has been used to treat periodontal disease due to its unique ability to reduce degeneration of collagenous matrix by inhibiting to reduce degradation of collagenous matrix by inhibiting the matrix metallo proteinases(MMP[s]) .[6] Golub et al [6] suggested that a systemic regimen of Subgingival Dose Doxycycline which reduced matrix metallo proteinases activity and alveolar bone resorption in patients with chronic periodontitis.

Bisphosphonates are potent inhibitors of bone resorption, and osteoporosis. [7] Reddy et al [8] did a study on beagle dogs and results revealed that systemic administration of bisphosphonate was beneficial in preventing alveolar bone destruction in periodontal disease.

In a recent animal study it was demonstrated that Chemically Modified Tetracycline with bisphosphonate is synergistically effective when delivered systematically. The topical delivery of Alendronate and other bisphosphonates also resulted in reduction of alveolar bone resorption. [9]

In present study the comparative efficacy of 1% Alendronate gel and Tetracycline fibers as an adjunct to scaling and root planing was assessed.

MATERIALS AND METHOD: The present research was carried out in accordance with Helsinki guidelines [10]. The study was conducted in the Department of Periodontics at I.T.S Dental College, Hospital and Research Centre, Greater Noida. 30 patients (18 males and 12 females) were included in the study .written informed consent was obtained from all the patients enrolled for the study. Ethical clearance was obtained from Institutional ethical committee, ITS Dental College, Greater Noida. (Letter No: IEC/PERIO/38/13)

Inclusion criteria:

1. Two sites located in separate quadrants that required periodontal therapy with minimum 20 teeth in oral cavity in a age group of 20-55 years and

2. Had not received any surgical and non surgical periodontal therapy since past 6 months back.

3. The sites with a residual pocket depth ≥ 4 mm at least one interproximal sites post 7 days following scaling and root planing.

Exclusion criteria:

1. Had a history of any antimicrobial therapy in past 3 months.

2. Had received any surgical and non surgical therapy in past 6 months

3. With any deleterious habits like tobacco chewing, smoking etc.

4. With any known systemic disease and condition known to cause periodontol disease like Diabetes, osteoporosis etc.

Clinical methods: A total of patients i.e 60 sites were selected and randomly grouped into two categories- Test and Control group .The Test group (30 sites) were treated with scaling and root planing(SRP) followed by local drug delivery 1% Alendronate gel (**Fig. 1** and **3**).The 1% ALN Gel was formulated by (Ovation REMEDIES, Ambala (Nahan) H.P) in the year 2012 with shelf life of approx.3 years.

FIG. 1: 1% ALENDRONATE GEL

FIG. 3: GROUP 1- PLACEMENT OF 1% ALENDRONATE GEL IRT 16

And Control group (30 sites)was treated with scaling and root planing(SRP) followed by local drug delivery of Tetracycline fibers(Periodontal Plus AB™ Advanced Biotech Products(P) Ltd, Tamil Nadu, India) (**Fig. 2** and **4**).

FIG. 2: TETRACYCLINE FIBERS (PERIODONTOL PLUS AB™)

FIG. 4: GROUP II- PLACEMENT OF TETRACYCLINE FIBERS IRT 26

All the patients were subjected to scaling and root planing at baseline measurement prior to scaling and root planing and after 6 months each selected site was assessed for the following clinical parameters:

1-Navy Plaque Index [11]
2-Gingival Index [12]
3-Clinical Probing Depth [12]
4-CAL(Clinical Attachment Level) [13]

After recording the clinical parameters at each site, in selected patients scaling and root planing was done at both the sites using ultrasonic scalers. One week after scaling and root planing placement of tetracycline fibers on one side and placement of 1% Alendronate gel on the other side was done.

At each visit (baseline,1,3 and 6 months)clinical parameters were assessed. The evaluation of plaque was done by using Navy plaque index [11] (Grossman FD and Fedi PF1970). Gingival index [12] (loe and sillness1964) was evaluated for each site.

Clinical probing depth (PD) was measured with the help of UNC 15 Periodontol probe (Hu-Friedy, Chicago, IL, USA). Acrylic stents were used in the study to reduce measurement error CAL (clinical attachment level) was measured. After placing the occlusal acrylic stent over the selected tooth, the periodontal probe was gently inserted along the groove on the acrylic stent. While recording the gingival index the tissue surrounding each tooth was divided into four gingival scoring units namely: distal, facial, mesial and lingual. Totaling the scores around each tooth yielded the gingival index (GI) score for the area. And the scores around each tooth were totaled and divided by four, the Gingival index (GI) score for the tooth was obtained.

Statstical Analysis: Descriptive data were presented as mean ± Standard deviation (SD) and range values. The analysis of variance(ANOVA) test was used to compare the result between the groups. A confidence interval of 95% was taken to consider a significance level at p value ≤ 0.05. Statstical analysis was performed using SPSS software (SPSS, IBM, Chicago, IL, USA).

RESULTS: A total of 30 patients enrolled at baseline completed the evaluation. A total no. of 60 sites with periodontal pocket measuring (4-7mm) in quadrants were selected. The selected sites were divided into control and test groups.

A comparison of Plaque index, Gingival index, CAL and Probing depth were evaluated from baseline to 6 months. The mean plaque score on baseline was 1.916±0.503 and on 6 months was 1.253±0.605 for test group.

The mean Plaque index at baseline was 2.05±0.66 and at 6 months was 1.020±0.946 for control group. The mean reduction of plaque index from baseline to six months was 0.663±1.52 for group I and .030±.155 for group II. On comparison the reduction of plaque score between test and control group, the mean reduction in test group was statistically significant ($p \leq 0.001$).

The mean Gingival score on baseline for group I was 2.163±0.458 and at 6 months 1.223±0.283 and for group II the mean gingival value at baseline was2.087±0.79 and on 6 months was 1.090±0.74. The mean reduction of Gingival index from baseline to six months for group I was 0.940±0.96 and for group II was 0.997±0.105.On comparison of reduction of gingival score between test and control group the mean reduction in test group was statistically significant ($p \leq 0.001$).

The mean Clinical probing depth on baseline was baseline was 4.260±0.52 and on 6 months was 2.60±0.62 for group I and for group II at baseline was 4.23±0.43 and on 6 months was 2.93±0.44. The mean reduction in probing depth from baseline to 6 months for group I was 1.667±0.130 and for group II was 1.300±0.109.On comparison of pocket probing depth reduction between test and control

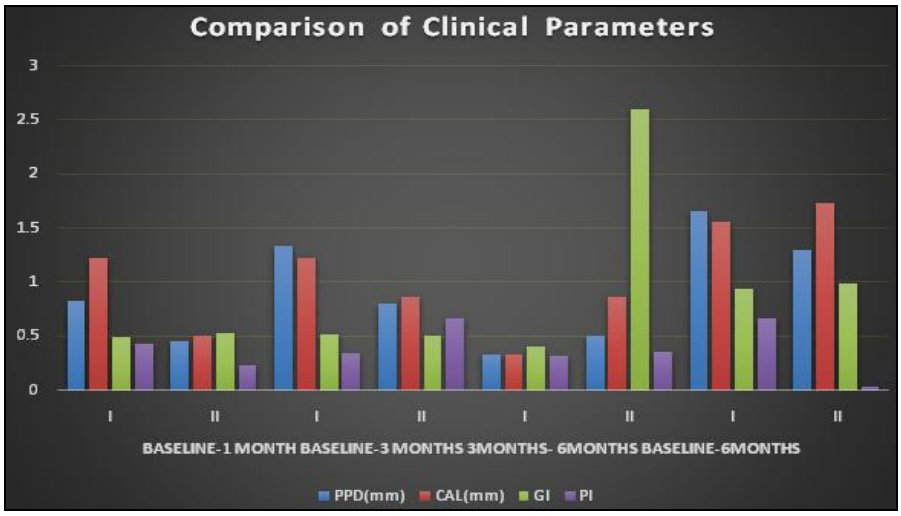
group, the test group shows significant results ($p \leq 0.003$).

The mean CAL at baseline was 3.266±0.58 and at 6 months was 1.70±0.53 for group I and for group II at baseline was 3.466±0.115 and for 6 months was 1.73±.135. The mean gain in CAL for group I from baseline to 6 months was 1.567±0.124 and for group II was 1.733 ±0.151. The mean gain in CAL for test group was highly significant with P value of ($p \leq 0.001$).

TABLE 1a: COMPARATIVE ANALYSIS OF ALL CLINICAL PARAMETERS FROM INTERVALS AT BASELINE TO 6 MONTHS

Parameters	Baseline- 1 Month		Baseline -3 Months		3 -6 Months		Baseline-6 Months	
	T	C	T	C	T	C	T	C
PD(mm)	0.83 ±0.10	0.46±0.12	1.33±0.13	0.80±0.11	0.33±0.13	0.50±0.13	1.66±0.13	1.30±0.10
p value	0.008*		0.006*		0.94		0.002*	
CAL(mm)	1.22±0.11	0.50±0.12	1.23±0.14	0.86±0.12	0.33±0.88	0.86±0.17	1.56±0.12	1.73±0.15
p value	0.002*		0.001*		0.001*		0.005*	
GI	0.49±0.89	0.53±0.13	0.52±0.15	0.51±0.13	0.41±0.12	2.6±2.7	0.94±0.96	0.99±0.10
p value	1.00		0.005*		0.02*		0.01*	
PI	0.43±0.80	0.23±0.16	0.34±0.14	0.67±0.15	0.32±0.14	0.35±0.07	0.66±0.15	0.03±0.15
p value	0.045*		0.126*		0.011*		0.009*	

PD=Clinical Probing Depth, **CAL**= Clinical Attachment Level, **GI**=Gingival Index, **PI**=Navy Plaque Index



GRAPH 1b: COMPARATIVE ANALYSIS OF ALL CLINICAL PARAMETERS FROM INTERVALS AT BASELINE TO 6 MONTHS

PD=Clinical Probing Depth, **CAL**= Clinical Attachment Level, **GI**=Gingival Index, **PI**=Navy Plaque Index

DISCUSSION: This study was conducted to evaluate the efficacy of 1% Alendronate gel and tetracycline fibers as an adjunct to scaling and root planing. The study was conducted on 30 subjects with a split mouth randomized controlled clinical design. The efficacy was determined based on the clinical parameters of the two groups that is Group I (treated by 1% Alendronate gel) and Group II (treated by tetracycline fibers). In order to overcome the drawbacks associated with systemic and conventional mode of therapy, local drug delivery system were administered, which were used in this study. Most widely used local drug delivery system in periodontal literature is Tetracycline as reported by Goodson. [14] Tetracycline inhibits collagenase activity, collagen degradation and bone resorption as reported by Golub *et al*. [15] They exert their antimicrobial effect by inhibiting microbial protein synthesis. In the present study the results showed statistically significant reduction in pocket probing depth (PPD) from baseline to 6 months in both the Test and the Control groups. (*p*=0.002).

Similarly, in both the Test and the Control groups there was a statistically significant gain in clinical attachment level (*p*=0.001). Although Group I i.e Test group revealed better results than Group II i.e

Control group but was not found to be statistical significant(p=0.788). Since the study was a split mouth design, the results of the indices revealed an overall reduction in scores of Gingival index and Navy plaque index in both groups at intervals from baseline to 6 months.(p=0.003)

Till date there are no studies reported in literature where the efficacy of 1%Alendronate gel and Tetracycline fibers have been compared as Local drug delivery (LDD) in a split mouth design. Although many authors have substantiated improvement in the clinical parameters such as CAL and Probing depth using Alendronate Gel and Tetracycline Fibers in different treatment modalities, either alone or with placebo or compared with some other drugs. Study which supported our results was done by Gill H.S., Bharti V., Gupta H., Gill S. [16] They compare the clinical efficacy of Tetracycline fibers and a xanthan based chlorhexidine gel in the treatment of chronic periodontitis. The results revealed that in both groups, there was statistically highly significant reduction in all the clinical parameters i.e Plaque score, Bleeding score, Probing pocket depth and Relative attachment level gain recorded at different time intervals.

In the present study Tetracycline fibers as a test group and 1% Alendronate gel in another group as local drug delivery agent and 1% Alendronate gel (ALN) shows better results in all clinical parameters (Clinical probing depth, Clinical attachment level, Navy plaque index, Gingival index) at intervals from baseline to 6 months.

Similarly, Pradeep and Co workers.[17, 18] also carried out a study to explore the efficacy of a 1%Alendronate gel compared to a placebo as a local drug delivery system and found that mean PD reduction and CAL gain was greater in ALN group than in the placebo group at 2 and 6 months our study corroborates with the findings of above mentioned studies.

Other studies supporting our results were that of Rocha M et al. [19] who found highly significant improvement as compared to placebo group with the Alendronate gel group with respect to the probing depth, clinical attachment level and gingival inflammation.

Similar studies were carried out on animal models before the human trials were undertaken but a few revealed contradictory results to the present study.

Brunsvold MA et al. [20] in a monkey model of periodontitis treated with Alendronate did not observe an effect on probing depth measurement. As per the results of present study, there was significant improvement in all clinical parameters with the Alendronate group having comparatively better result than Tetracycline group. The Alendronate group has an upper hand in terms of periodontal therapy since it gives a maximum reduction in all clinical parameters. Alendronate is known to act on the bone surface for inhibition of the osteoclastic activity. Within limits superimposed by a relatively smaller sample size, the present study shows improvements in clinical parameters both in Group I and II. However, the Group I showed better result in terms of Clinical Attachment Level gain, Clinical probing depth and Indices.

SOURCE OF SUPPORT: Nil.

CONFLICT OF INTEREST: None declared.

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