



## EFFICACY OF 1% ATORVASTATIN DENTIFRICE AS AN ADJUNCT TO NON SURGICAL PERIODONTAL THERAPY IN CHRONIC PERIODONTITIS

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### ABSTRACT

**Aim:** To clinically evaluate the effect of 1% atorvastatin dentifrice in adjunct to scaling and root planing in Chronic Periodontitis and to compare its efficacy with placebo dentifrice

**Materials and Methods:** 70 Chronic Periodontitis patients aged between 30 to 60 years with minimum of 14 teeth present were selected from OPD of Department of Periodontology, FDS, RUAS, Bangalore for the study. The study population was divided into two groups. Group A (n=35) 1% atorvastatin dentifrice in adjunct to NSPT. Group B (n=35) placebo dentifrice in adjunct to NSPT. Clinical Parameters (GI, PI, PPD, CAL) were assessed at baseline and 1 month.

**Result:** Statistically significant improvement was seen in clinical parameters (GI, PI, PPD, CAL) at one month in both the groups. On intergroup comparison, statistically significant difference was noted in values of GI, PI, PPD, CAL between Group A and Group B at 1 month wherein Group A demonstrated better results when compared to Group B

**Conclusion:** 1% Atorvastatin dentifrice used as an adjunct to NSPT showed better clinical efficacy than placebo group in Chronic Periodontitis patients.

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### INTRODUCTION

Periodontal diseases form a major dental health problem. The common approach used in the treatment of periodontal disease is, based primarily on the control of the etiologic agent such as bacterial biofilm, which has not been sufficient to reduce the high prevalence of periodontal disease. The emerging understanding regarding the role of host immune response in periodontal tissue breakdown and the specific inflammatory mechanism involved have encouraged researchers to explore new strategies in the management of periodontal disease.

Various broad spectrum antibiotics have been tried and found to have an inhibitory effect on both caries and periodontitis but their prolonged use is not a practical solution to plaque control as it leads to undesirable side effects like resistant strains and sensitization when tried both systemically and topically. Recently, improvements have been reported in the status of periodontal disease associated with the use of statins. Statins are effective lipid-lowering agents with additional effects that are beneficial in treating periodontal disease, such as anti-inflammatory properties, stimulation of bone formation, and immunomodulatory actions (4).

Recently, clinical trials have shown improvement in periodontal clinical parameters using 1.2% atorvastatin or 1.2% simvastatin as a biodegradable controlled-release gel adjunct to scaling and root planing in the treatment of Chronic Periodontitis, observing greater improvement with the use of atorvastatin (3). Despite of all this, there remains a lack of information regarding the best vehicle, most appropriate doses, and confirmation of the true effects of statins in periodontal disease. Considering that dentifrice is the most used complement in oral hygiene techniques, dentifrice could be an effective medium to release statins, especially atorvastatin, which has demonstrated a greater topical effect. Hence the aim of the study would be to clinically evaluate the effect of 1% atorvastatin dentifrice in adjunct to scaling and root planing in Chronic Periodontitis

### MATERIALS AND METHODS

60 Patients who reported to Department of Periodontology, Faculty of Dental Sciences, Ramaiah University of Applied Sciences between November 2016 and December 2016 were enrolled in the study based on inclusion and exclusion criterias. Ethical Clearance was obtained from college ethical committee board. Sample size was determined using a formula which considered the power of the study to be 80% with 5% error. Patient within age group of 30 – 60 years of both sexes with atleast 14 teeth excluding 3<sup>rd</sup> molar who were diagnosed with Chronic Generalized Periodontitis (Armitage 1999) and have probing pocket depth of  $\leq 5$  mm and Clinical attachment

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loss  $\leq$  4 mm were included in the study. Whereas, patients receiving antibiotic therapy or non-steroidal anti-inflammatory drugs during the previous 2 months or using calcium channel blockers, phenytoin, cyclosporine, or any associated drug that might affect gingival tissue, or who had undergone Periodontal treatment during the previous 12 months, or patients who were suffering from Autoimmune disorders, or who had uncontrolled or poorly controlled diabetes or who were undergoing systemic statin treatment were excluded from the study.

It is double blinded interventional study. Patients were divided into two groups after randomization using sealed envelopes for assigning treatment group to the patients and informed consent was obtained from all the patients. In Group A, patients underwent Scaling and Root planing followed by which they were given self formulated (at Faculty of Pharmacy, Ramaiah University of Applied Sciences) 1% atorvastatin dentifrice. Whereas in Group B, patients underwent Scaling and Root planing followed by which they were given similarly packaged self formulated (at Faculty of Pharmacy, Ramaiah University of Applied Sciences) placebo dentifrice. Clinical Parameters i.e. Bleeding index (Muhlemann, 1976), Gingival index (Loe and Silness, 1964), Probing pocket depth and Clinical attachment loss were recorded at baseline and after 1 month of Phase I therapy in all the patients using UNC-15 Probe.

**RESULTS**

Out of 60 patients who were included in the study, 30 were in Group A and 30 were in Group B. 59.4% of Participants in Group A were males, whereas 40.6% were females. Similarly in Group B, 64% participants were males and 36% participants were females. Mean age of the population in group A was reported to be 42.8 and 45.4 for group B.

At baseline, there was no statistical difference in the mean values of Gingival Index, Papillary bleeding index, probing pocket depth, clinical attachment level between Group A and Group B (Table 1). At 1 month, statistically significant difference was noted in the mean values of Gingival Index, Papillary bleeding index, probing pocket depth, clinical attachment level between Group A and Group B. Group B had consistently lower values of all the parameters when compared to Group A (Table 2, Graph 1), which shows greater improvement in clinical parameters in Group B when compared to Group A.

**Table 1** Comparison of mean values of study variables between group A & group B at Baseline period using Independent Student t Test

Variables	Group	N	Mean	SD	S.E.M	Mean Diff	t	P-Value
GI	Group A	32	1.97	0.06	0.01	0.04	1.751	0.09
	Group B	25	1.93	0.12	0.02			
PBI	Group A	32	1.94	0.09	0.02	0.02	0.757	0.45
	Group B	25	1.92	0.13	0.03			
PD	Group A	32	4.73	0.20	0.04	-0.04	-0.651	0.52
	Group B	25	4.76	0.21	0.04			
CAL	Group A	32	5.38	0.57	0.10	0.12	0.678	0.5
	Group B	25	5.26	0.75	0.15			

**Table 2** Comparison of mean values of study variables between group A & group B at 1 month Post treatment period using Independent Student t Test

Variables	Group	N	Mean	SD	S.E.M	Mean Diff	t	P-Value
GI	Group A	32	1.00	0.00	0.00	-0.17	-6.985	<0.001*
	Group B	25	1.17	0.14	0.03			
PBI	Group A	32	1.03	0.07	0.01	-0.11	-4.690	<0.001*
	Group B	25	1.14	0.11	0.02			
PD	Group A	32	0.94	0.34	0.06	-2.56	-23.977	<0.001*
	Group B	25	3.50	0.47	0.09			
CAL	Group A	32	2.45	0.33	0.06	-1.48	-12.618	<0.001*
	Group B	25	3.93	0.55	0.11			

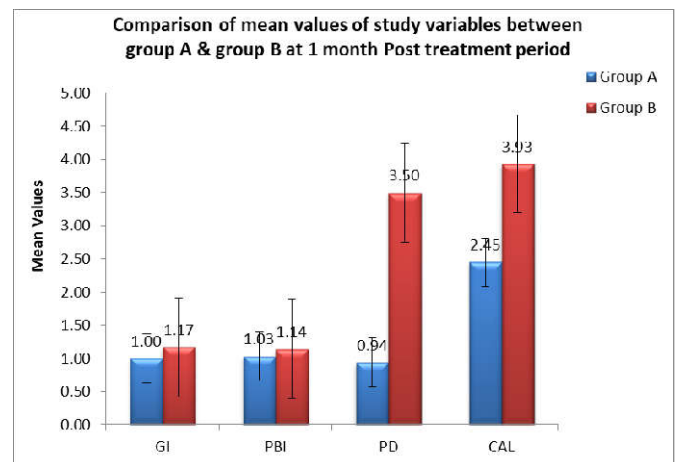
On comparing the mean values of clinical parameters in Group A at baseline and 1 month, it was noted that there was statistically significant decrease in all the values over one month in Group A (Table 3, Graph2). On comparing the mean values of clinical parameters in Group B at baseline and 1 month, it was noted that there was statistically significant decrease in all the values over one month in Group B (Table 4, Graph 3)

**Table 3** Comparison of mean values of study variables between baseline & 1 month post Rx period in Group A using Paired Student t Test

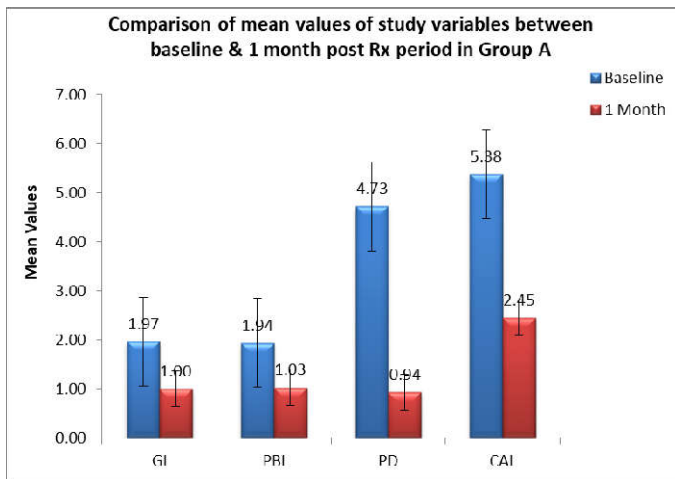
Variables	Time	N	Mean	SD	S.E.M	Mean Diff	t	P-Value
GI	Baseline	32	1.97	0.06	0.01	0.97	87.034	<0.001*
	1 Month	32	1.00	0.00	0.00			
PBI	Baseline	32	1.94	0.09	0.02	0.91	49.851	<0.001*
	1 Month	32	1.03	0.07	0.01			
PD	Baseline	32	4.73	0.20	0.04	3.79	52.616	<0.001*
	1 Month	32	0.94	0.34	0.06			
CAL	Baseline	32	5.38	0.57	0.10	2.93	25.898	<0.001*
	1 Month	32	2.45	0.33	0.06			

**Table 4** Comparison of mean values of study variables between baseline & 1 month post Rx period in Group B using Paired Student t Test

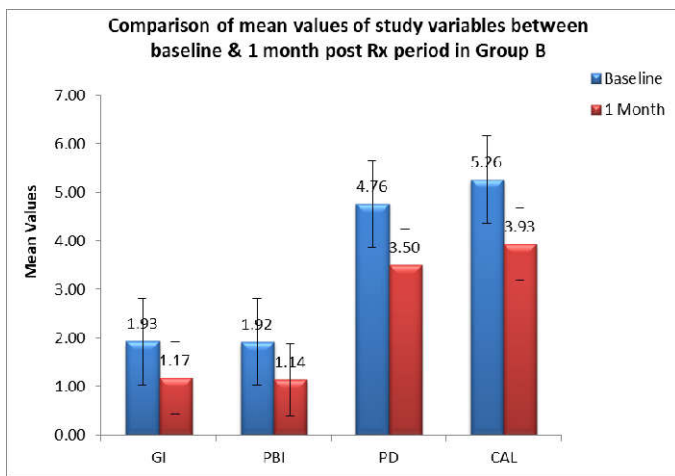
Variables	Time	N	Mean	SD	S.E.M	Mean Diff	t	P-Value
GI	Baseline	25	1.93	0.12	0.02	0.75	24.822	<0.001*
	1 Month	25	1.17	0.14	0.03			
PBI	Baseline	25	1.92	0.13	0.03	0.78	25.914	<0.001*
	1 Month	25	1.14	0.11	0.02			
PD	Baseline	25	4.76	0.21	0.04	1.27	15.620	<0.001*
	1 Month	25	3.50	0.47	0.09			
CAL	Baseline	25	5.26	0.75	0.15	1.33	11.840	<0.001*
	1 Month	25	3.93	0.55	0.11			



**Graph 1** Comparison of mean values between group A & group B at 1 month Post treatment



Graph 2 Comparison of mean values between baseline & 1 month post Rx period in Group A



Graph 3 Comparison of mean values between baseline & 1 month post Rx period in Group B

## DISCUSSION

In subjects susceptible to periodontal disease, meticulous, self-performed, supragingival plaque control maintained over a long period of time has been proved to prevent recurrent periodontitis. (6,7,8) Dentifrice has been an integral unit of patient performed mean of plaque control (9). In the present study, adjunctive use of atorvastatin dentifrice with non surgical periodontal therapy resulted in significantly improved clinical parameters when compared to placebo group. These results are in accordance with a study done by David R. Rosenberg (2015) *et al* where it was found that Non Surgical Periodontal Therapy plus 2% atorvastatin medicated dentifrice was more effective in improving clinical periodontal parameters than Non Surgical Periodontal Therapy plus a placebo dentifrice. (5) A lesser concentration of atorvastatin was used in the present study to find the least concentration of atorvastatin in dentifrice which can be effective in periodontitis cases.

Another study by A.R.Pradeep (2013) *et al* on 60 patients where 1.5% atorvastatin was administered to periodontitis patients in the form Local Drug delivery, it was found that Mean Probing pocket depth reduction and mean Clinical attachment level gain were greater in the Atorvastatin group than the placebo group at 3, 6, and 9 months. A significantly greater mean percentage of radiographic bone fill was found in

the Atorvastatin group compared to the placebo group after 9 months.(3)

Statins were found have positive impact on periodontal health in various studies. J. Cunha-Cruz (2006) in his study concluded that there is an association of statin use with reduced tooth loss in chronic periodontitis patients. (4) According to a study by Sharath (2013), High-dose atorvastatin reduces periodontal inflammation, suggesting a newly recognized effect of statins.(1) According to a systematic review by Professor Maria Mônica Studart Mendes Moreira (2015), Statins have important anti-inflammatory and immune effects, reducing levels of C-reactive protein and matrix metalloproteinases and their intermediate products, such as tumour necrosis factor- $\alpha$ , and are also able to inhibit the adhesion and extravasation of leukocytes, which block the co-stimulation of T cells. Statins reduce bone resorption by inhibiting osteoclast formation and lead to increased apoptosis of these cells. The effect of statins on bone formation is related to the increased gene expression of bone morphogenetic protein in osteoblasts. (2)

## CONCLUSION

1% Atorvastatin dentifrice as an adjunct to non surgical periodontal therapy shows better clinical result than placebo as an adjunct to non surgical periodontal therapy in Chronic Periodontitis patients. Multi-nodal studies should be conducted with other different concentrations of atorvastatin in dentifrice to confirm the result.

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