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ORIGINAL ARTICLE

TO COMPARE THE CLINICAL EFFICACY OF COMMERCIALLY AVAILABLE DENTIFRICE VIZ PARODONTAX®, PARODONTAX® WITH SCALING AND SCALING ALONE IN PATIENTS WITH GINGIVITIS: A RANDOMIZED CONTROLLED CLINICAL TRIAL

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ABSTRACT: BACKGROUND: Incorporating herbal extracts in the formulation of toothpastes is becoming an accepted mode of chemical plaque control. Parodontax® is a herbal toothpaste designed to reduce bleeding gums and prevent gingivitis and periodontitis. The aim of the present study is to compare the clinical efficacy of commercially available dentifrice viz Parodontax®, Parodontax® with scaling and scaling alone. **MATERIAL AND METHODS:** Ninety patients with gingivitis had been referred to the Department of Dentistry, Adhichunchanagiri Institute of Medical Sciences. The subjects were randomly allocated into 3 groups. Group I- Parodontax® tooth paste only (n=30), Group II-Parodontax® with scaling (n=30), Group III–scaling only (n=30). Clinical parameters were assessed using Gingival Index, Plaque Index and Bleeding Index at baseline, 4 and 6 weeks. **OBSERVATIONS:** The results of the present study therefore have confirmed the effectiveness of initial therapy, in the form of repeated oral hygiene instruction and thorough scaling and root planning in conjunction with Parodontax, in significantly reducing the clinical parameters of gingivitis and periodontal disease. **CONCLUSION:** The present study revealed that when Parodontax used in conjunction with scaling and root planning has shown to be effective anti-plaque agent. Further, the combined use of parodontax with scaling and root planning has been shown to reduce gingival inflammation and sulcular bleeding significantly over 6months period. However, it is important for therapeutic products to be tested within the context of their possible use. Therefore Parodontax used as an adjunct to convention universal therapy in the treatments of patients with varying degrees of gingival and periodontal diseases, it is important for these products to be tested accordingly.

KEYWORDS: Gingivitis, Parodontax, Scaling and root planning, Plaque, Bleeding on probing.

INTRODUCTION: Periodontal diseases encompass multifactorial diseases involving bacterial biofilms and the generation of an inflammatory response, including the production of cytokines, eicosanoids, and matrix metalloproteinases. Bacterial biofilms have been shown to be the primary etiological factor in the initiation of gingival inflammation and subsequent destruction of periodontal tissues.[1] It is well established that supragingival plaque is the cause of gingivitis and plays a primary role in the initiation of periodontitis[2]. The removal of microbial plaque leads to resolution of gingival inflammation, and cessation of plaque control leads to a recurrence of inflammation.[3]

Treatment planning in periodontics should be based on an understanding of the etiology and pathogenesis of periodontal disease. The future treatment should be determined by an assessment of disease activity following resolution of the marginal inflammation. Hence, one of the aims of initial periodontal therapy is to reduce marginal inflammation so as to allow residual disease to be assessed

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and treated. As supragingival plaque control, in conjunction with supragingival and subgingival scaling, is necessary to reduce marginal inflammation, an effective antiplaque agent may be a beneficial adjunct in the early stages of therapy with a patient is developing effective plaque control skills

Supragingival plaque control is an effective method of controlling gingivitis and is an important component of periodontal therapy. Undoubtedly, the most widely practiced form of oral hygiene is tooth brushing with a dentifrice. It has been estimated that less than one third of the population of developed nations can be expected to practice adequate mechanical plaque removal. Therefore, it could be argued that supplementation of mechanical brushing with effective adjunctive chemotherapeutic agents would be beneficial to gingival health.

One of the most effective agents for supragingival plaque control is chlorhexidine. However, a significant reduction of its antiplaque potential may be observed when it is used in a toothpaste preparation. Triclosan has also been incorporated into dentifrices, and some studies have demonstrated a significant reduction of plaque and gingivitis.

In many countries and among certain nations, there is a tendency towards using plant-based products especially of their long-term and routine application is intended. It is estimated that 25% of prescriptions written in the US contain plant-derived ingredients, while 75-90% of the rural population of the rest world still relies on herbal medicine as their only health care.[4]

Parodontax® (GlaxoSmithKline, Middlesex, United Kingdom) has received great attention. It is composed of sodium bicarbonate, sodium fluoride (1, 400 ppm) and herbal ingredients: chamomile, which is supposed to have anti-inflammatory properties and to decrease gingival inflammation; Echinacea, which is reputed to stimulate the immune response; sage and rhatany, which have anti-hemorrhagic properties; myrrh, claimed to be a natural antiseptic; and peppermint oil, which has analgesic, antiseptic and anti-inflammatory properties.

Some studies have reported that Parodontax® is able to significantly decrease plaque and gingivitis, while other publications showed no effectiveness of the dentifrice when compared to a control.

The aim of this study was to evaluate clinical effects of commercially available dentifrice viz parodontax®, parodontax® with scaling and scaling alone in the reduction of plaque, gingivitis and gingival bleeding in subjects with gingivitis with or without periodontitis.

MATERIALS AND METHODS: Ethical approval was obtained from the Institutional Ethical Committee and Review Board. A total of 45 dentate subjects (23 males, 22 females, mean age years) who reported to the Department of Dentistry, Adicunchanagiri Institute of Medical College & Hospital, B G Nagara, were recruited for this double-blinded, randomized controlled clinical trial conducted from January 2014 to June 2014. All randomly screened participants were informed about the study and signed an informed consent form.

Subjects diagnosed with chronic generalized gingivitis with or without periodontitis, aged 20-40 years, having at least 20 natural teeth, and with no history of periodontal therapy or previous use of antibiotics or anti-inflammatory medication within the preceding 6 months were included in the study. All patients fulfilled the clinical criteria of the plaque index (Silness & Loe) ≥ 1, gingival index (Loe & Silness) ≥ 1, bleeding index (Ainamo & Bay) > 30%, pocket probing depth ≤ 3 mm, clinical attachment loss = 0, with no evidence of radiographic bone loss. Subjects with known allergies to the

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constituents of the formulation, hematological disorders or other systemic illnesses, pregnant and lactating females, those undergoing orthodontic treatment and smokers were excluded.

The participants were assigned randomly by drawing chits to one of three groups (15 subjects in each group): Group 1: Scaling alone, Group 2: Scaling and Parodontax® dentifrice, and Group 3: Parodontax® dentifrice alone.

At baseline, the amount of plaque, gingival inflammation and gingival bleeding was measured on all teeth. The participants were stained for plaque using an erythrosine disclosing solution and cotton swabs. The amount of plaque was scored using the Silness & Loe plaque index (1964). After that, gingival inflammation was recorded using the Loe & Silness gingival index (1963). Gingival bleeding was recorded using the criteria of the Ainamo & Bay bleeding index (1975). All measurements were carried out by a single calibrated investigator (S.S.P).

Following scoring, the subjects in Group 1 underwent scaling by a trained clinician (R.M.P). Subjects in Group 2 received the test dentifrice (Parodontax® dentifrice) in addition to undergoing scaling by the same clinician. Group 3 subjects on the other hand, only received the Parodontax® dentifrice. Subjects were instructed to brush twice daily with the supplied dentifrice (in case of Group 2 & 3) while Group 1 subjects used their regular dentifrice. Further, the subjects were instructed to use the modified bass method of brushing and refrain from all other forms of oral hygiene aids during the study.

Subjects were again assessed for the amount of plaque, gingival inflammation and gingival bleeding at 4 weeks and 6 weeks. To check for compliance, the subjects were asked to return the dentifrice tubes, so that the investigators could verify the amount of dentifrice that was used.

Statistical Analyses: Analysis of data was carried out using SPSS version 13. The values of different parameters collected are expressed as means ± standard deviation (SD). Paired-t test was used to compare data at baseline, 4 weeks and 6 weeks.

Statistical software was used to analysis the data. Analysis of data was carried out using SPSS version 13. The values of different parameters collected are expressed as means±SD. Paired-t test used to compare data between baseline, after 4 weeks and 6 weeks. ANOVA test was used to comparison of different clinical parameters such as Plaque Index (PI), Gingival Index (GI). McNemar's test used to compare Bleeding on probing (BOP). Chi-square test used to compare BOP at baseline, after 4 weeks and 6 weeks.

OBSERVATIONS: A one way ANOVA done across the groups' shows that there was no significant difference in the baseline PI and GI. Thus subjects were comparable in their baseline characteristic. Significant difference was noted in the PI and GI scores at 4^{th} week and 6^{th} week respectively. Table 3 and 4 shows the results of PI and GI scores respectively across the groups.

There was a significant difference in the PI scores between group 2 and 3 (mean difference of 0.46±0.51 and 2.26±0.45) at 4^{th} week. At the 6^{th} week there was significant difference in the mean score between group 2 and 1 (mean difference of 0.33 ± 0.48 and 1.6 ±0.5) and p value <0.05), between group 2 and 3 (mean difference of 0.33 ± 0.48 and 1.66 ± 0.72, p value of <0.05).

The results of repeated measures ANOVA showed that there was a significant reduction in PI and GI between the baseline, fourth and sixth week across all the groups. The maximum reductions in the scores were seen in group 2 as compared to group 1 and 3.

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With regards to BOP scores, there was statistical significant reduction in all groups at all-time intervals. However, the greatest reduction in BOP was seen in group 2 than group 1 and 3(Table 5).

TABLE 1: CLINICAL PARAMETERS COMPARISION BETWEEN BASELINE, 4 WEEKS AND 6 WEEKS AFTER ORAL- PROPHYLAXIS USING PAIRED- T TEST (GROUP 1).

ORAL PROPHYLAXIS		MEAN ±SD	Df	P VALUE
PLAQUE INDEX	BASELINE	2.66 ±0.48	14	<0.001**
	4 WEEK	1.4 ±0.5		
	4 WEEK	1.4 ±0.5	14	0.18
	6WEEK	1.6 ±0.5		
	BASELINE	2.6 ±0.48	14	<0.001**
	6 WEEK	1.6 ±0.5		

ORAL PROPHYLAXIS		MEAN	Df	P VALUE
GINGIVAL INDEX	BASELINE	2.4 ±0.5	14	<0.001**
	4 WEEK	1 ±0.6		
	4 WEEK	1 ±0.6	14	0.04
	6WEEK	0.73 ±0.45		
	BASELINE	2.4±0.5	14	<0.001**
	6 WEEK	0.73±0.45		

ORAL PROPHYLAXIS		BOP PRESENT %	BOP ABSENT %	P VALUE
BOP	BASELINE	13(86.6)	2(13.3)	0.025
	4 WEEK	8(53.3)	7(46.6)	
	4 WEEK	8(53.3)	7(46.6)	0.025
	6WEEK	10(66.6)	5(33.3)	
	BASELINE	13(86.6)	2(13.3)	0.005*
	6 WEEK	10(66.6)	5(33.3)	

TABLE 2: CLINICAL PARAMETERS COMPARISION BETWEEN BASELINE, 4 WEEKS AND 6 WEEKS AFTER **ORAL- PROPHYLAXIS AND PARODONTAX TOOTH PASTE** USING PAIRED- T TEST (GROUP 2).

ORAL PROPHYLAXIS + PARODONTAX TOOTH PASTE		MEAN ± S.D		P VALUE
PLAQUE INDEX	BASELINE	2.8 ± 0.41	t= 14.64	<0.001**
	4 WEEK	0.46 ± 0.51		
	4 WEEK	0.46 ± 0.51	t=1	0.33
	6WEEK	0.33 ± 0.48		
	BASELINE	2.6 ± 0.41	t= 14.92	<0.001**
	6 WEEK	0.33 ± 0.48		

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ORAL PROPHYLAXIS + PARODONTAX TOOTH PASTE		MEAN ± S.D		P VALUE
GINGIVALINDEX	BASELINE	2.6 ± 0.50	t= 9.05	<0.001**
	4 WEEK	0.53± 0.51		
	4 WEEK	0.53± 0.51	t=2.64	0.019
	6WEEK	0.2 ± 0.41		
	BASELINE	2.6 ± 0.50	t= 11.22	<0.001**
	6 WEEK	0.2 ± 0.41		

ORAL PROPHYLAXIS + PARODONTAX TOOTH PASTE		BOP PRESENT%	BOP ABSENT%	P VALUE
BOP	BASELINE	13(86.6)	02(13.3)	0.005
	4 WEEK	5(33.3)	10(66.6)	
	4 WEEK	5(33.3)	10(66.6)	0.04
	6WEEK	1(6.6)	14(93.3)	
	BASELINE	13(86.6)	02(13.3)	<0.001**
	6 WEEK	1(6.6)	14(93.3)	

TABLE 3: CLINICAL PARAMETERS COMPARSION BETWEEN AT BASELINE, 4 WEEKS AND 6 WEEKS AFTER **PARODONTAX TOOTH PASTE** ALONE USING PAIRED- T TEST (GROUP 3).

PARODONTAX TOOTH PASTE ONLY		MEAN ± S.D		P VALUE
PLAQUE INDEX	BASELINE	2.8 ± 0.41	t= 4	<0.001**
	4 WEEK	2.26 ± 0.45		
	4 WEEK	2.26 ± 0.45	T=2.10	0.054
	6WEEK	1.66 ± 0.72		
	BASELINE	2.8 ± 0.41	T= 6.08	<0.001**
	6 WEEK	1.66 ± 0.72		

PARODONTAX TOOTH PASTE ONLY		MEAN ± S.D		P VALUE
GINGIVALINDEX	BASELINE	2.46 ± 0.63	t= 3.5	0.0017
	4 WEEK	2.0 ± 0.37		
	4 WEEK	2.0 ± 0.37	T=12.4	<0.001**
	6WEEK	1.86 ± 0.51		
	BASELINE	2.46 ± 0.63	T= 12.4	<0.001**
	6 WEEK	1.86 ± 0.51		

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PARODONTAX TOOTH PASTE ONLY		BOP PRESENT %	BOP ABSENT %	P VALUE
BOP	BASELINE	14(93.3)	01(6.6)	0.005
	4 WEEK	6(40)	9(60)	
	4 WEEK	6(40)	9(60)	0.180
	6WEEK	3(20)	12(80)	
	BASELINE	14(93.3)	01(6.6)	<0.001**
	6 WEEK	3(20)	12(80)	

TABLE 4: Plaque Index and Gingival index score Comparison between 3 groups at baseline, after 4 weeks and 6 weeks using ANOVA test

ANOVA TEST:

		F VALVE	p VALUE
PLAQUE INDEX	BASELINE	0.45	0.63
	4 WEEK	49.72	<0.001**
	6 WEEK	24.9	<0.001**

		F VALVE	p VALUE
GINGIVAL INDEX	BASELINE	0.505	0.60
	4 WEEK	30.14	<0.001**
	6 WEEK	50.33	<0.001**

BOP score comparison between different groups at baseline, 4weeks and 6 weeks using Table 5: CHI-SQUARE TEST

		X^2	P value
BOP	BASELINE	0.450	0.79
	4 WEEK	1.275	0.52
	6 WEEK	3.33	0.18

** Highly statistical significant

*Statistically significant

DISCUSSION: This study investigated the clinical efficacy of commercially available dentifrice viz parodontax®, parodontax® with scaling and scaling alone in patients with gingivitis. The results demonstrate that initial therapy in the form of oral hygiene instruction and education, supragingival and subgingival scaling and root planning leads to a significant improvement in all clinical parameters. Studies conducted by proye et al.[5] showed major reduction in mean plaque and gingival indices and a significant reduction in probing pocket depth in 1 week after a single episode of scaling and root planning. A further reduction in pocket depth and gain of attachment was seen after 3 weeks.

Mahanonda et al.[6] used both a gingivitis and an adult periodontitis (AP) group and showed that in the gingivitis group the overall reduction in gingival inflammation also resulted in a reduction of probing depths, presumably because of a reduction in gingival swelling, as there was no change in the loss of attachment. In the AP group the reduction in probing depths was not only accompanied by an improvement in gingival health but also by a significant gain of attachment. The present study also showed a significant decrease in probing depth which was maintained up to six weeks post therapy, but it is unknown whether this was due to resolution of the gingival inflammation or a result of a gain of attachment.[7]

Evans et al.[8] and Mahanonda et al.[7] showed that there was a significant increase in the number of sites with a GI of 0 or 1 (that is, not bleeding on probing) two weeks following the completion of initial therapy. The present study not only confirms these results but shows that concomitant with the increase in gingival health there is a significant increase in the number of plaque free sites. The present study also shows that this improvement in clinical parameters is maintained for at least six weeks post initial therapy.

The results of the present study therefore have confirmed the effectiveness of initial therapy, in the form of repeated oral hygiene instruction and thorough scaling and root planning in conjunction with Parodontax, in significantly reducing the clinical parameters of gingivitis and periodontal disease.

The present study revealed that when Parodontax used in conjunction with scaling and root planning has shown to be effective anti-plaque agent. Further, the combined use of parodontax with scaling and root planning has been shown to reduce gingival inflammation and sulcular bleeding significantly over 6months period. However, it is important for therapeutic products to be tested within the context of their possible use. Therefore Parodontax used as an adjunct to convention universal therapy in the treatments of patients with varying degrees of gingival and periodontal diseases, it is important for these products to be tested accordingly.

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