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Clinical Effects of Commerically Available Dentifrice Containing Aloe Vera versus Aloe Vera with Scaling and Scaling Alone: A Randomized Controlled Clinical Trial.

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ABSTRACT

Microbial biofilms and plaque are considered to be the primary etiological factors in the initiation of gingival inflammation which in turn leads to gingival and periodontal diseases. The rigorous self performed plaque control over a long period of time reduces the amount and alters the composition of microbial plaque. This in turn results in achieving a functionally healthy gingiva and periodontium. The aim of this single centered, randomized controlled clinical trial was to assess the clinical effects of commercially available dentifrice containing aloe vera versus aloe vera with scaling and scaling alone. A total of 45 dentate subjects (23 males, 22 females, mean age 25 years) were recruited for this randomized controlled clinical trial. The participants were assigned randomly by drawing lots to one of the three groups (15 subjects in each group): Group 1- Scaling alone, Group2-Aloe vera with scaling, Group 3-Aloe vera alone. All the clinical parameters such as probing pocket depth (PPD), gingival index (GI), and plaque index (PI) were assessed at baseline, 4 and 6 weeks after intervention. Significant difference was noted in the PI and GI scores at 4^{th} week and 6^{th} week respectively. There was a significant difference in the PI index between group 2 and 3 at 4^{th} week. At the 6^{th} week there was significant difference in the mean score between group 1 and 2 and between group 2 and 3. The results of repeated measures ANOVA showed that there was significant reduction in PI and GI at the baseline, fourth and sixth weeks across all the groups. Within the limits of the study, it can be concluded that Aloe Vera can be used as an adjunct to scaling (Oral prophylaxis) to obtain improvement in clinical parameters (PI, GI, BOP).

Keywords: dentrifice, Aloe vera, clinical trial

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INTRODUCTION

The various forms of gingival and periodontal diseases have affected humans since the dawn of history. Microbial biofilms and plaque are considered to be the primary etiological factors in the initiation of gingival inflammation which in turn leads to gingival and periodontal diseases. Many researchers have proved beyond doubt that microbial plaque causes the initiation and progression of gingivitis and periodontitis. The optimal elimination of microbial plaque leads to resolution of gingival inflammation and restores a functionally healthy gingiva [1].

The rigorous self performed plaque control over a long period of time reduces the amount and alters the composition of microbial plaque. This in turn results in achieving a functionally healthy gingiva and periodontium [1].

The deficiency in the method to perform adequate tooth brushing by the population has led to the search for chemotherapeutic agents as dentifrice to improve plaque control by cleaning and polishing tooth surfaces [1].

In the recent past, the use of natural products such as Aloe Vera as dentifrice has gained importance. The aloe plant contains anthraquinone, glycosides, polysaccharides, aloe resins, glucomannans, and β-sitosterol phenolic compounds. The therapeutic properties of Aloe Vera exhibits anti- inflammatory activity, astringent effect, ability to promote the wound healing and anti-microbial effect. The above properties along with ease of availability with no known adverse effects and cost effectiveness make aloe vera an ideal choice as dentifrice for microbial plaque control [2].

However, there is only limited data available which compares the clinical effects of a commercially available dentifrice containing aloe vera as monotherapy versus aloe vera with scaling and scaling alone.

Therefore considering the aforementioned findings, this 6 week, single centered, randomized controlled clinical trial was conducted to assess the clinical effects of commercially available dentifrice containing aloe vera versus aloe vera with scaling and scaling alone.

MATERIALS AND METHODS

A total of 45 dentate subjects (23 males, 22 females, mean age 25 years) who reported to Department of Periodontology, Rajarajeswari Dental College and Hospital, Bangalore, were recruited for this randomized controlled clinical trial conducted from April 2013 to October 2013. All participants were informed about the nature of the study and signed an informed consent. Ethical approval was obtained from the Institutional Ethical Committee and Review Board. A sample size of 45 gave 95% power and a significance level of 0.05.

Subjects who were diagnosed with chronic generalised gingivitis aged 25 - 40 years, having ≥ 20 teeth, with no history of periodontal therapy or previous use of anti-inflammatory medication within the preceding 6 months were included in this study. All patients fulfilled the clinical criteria of the gingival index (Loe and Silness, 1963) score of ≥1, plaque index (Silness and Loe, 1964) score of ≥1, bleeding index score of > 30% (Ainamo and Bay, 1975) and pocket probing depth ≤3mm, clinical attachment loss=0, with no evidence of radiographic bone loss. Subjects with known allergies towards the constituents of the formulation, haematological disorders or other systemic illness, pregnant and lactating females, undergoing orthodontic treatment and with smoking habits were excluded.

After the initial examination, all the teeth were polished with pumice and flossed to eliminate plaque remnants. A personal "kit" containing a new toothbrush (Colgate ZigZag; Bangalore, India) was given to all participants and for those in Group 2 and 3; dentifrice containing aloe vera was dispensed. They were instructed to brush their teeth for 2 minutes, two times a day, using the Bass technique, and to refrain from other oral hygiene procedures throughout the period of the clinical trial. Verbal and written instructions about the correct use of dentifrice were given to all subjects as well. The participants were assigned randomly by drawing lots to one of the three groups (15 subjects in each group):

Group 1: 15 patients treated with scaling alone (Oral prophylaxis)
Group 2: 15 patients treated with scaling (Oral prophylaxis) and ALOE VERA tooth paste (Rushivar Ayurvedic Company, Surat, India)
Group 3: 15 patients treated with ALOE VERA tooth paste alone.

STATISTICAL ANALYSES

Statistical Package for the Social Sciences (SPSS) was used to analyze the data. The values of different parameters collected are expressed as means ± SD. Repeated measure ANOVA was used to compare data between baseline, after 4 weeks and 6 weeks. One way ANOVA was used for comparison of different clinical parameters such as Plaque Index (PI), Gingival Index (GI) across the different groups. Chi-square test compared BOP at baseline, after 4 weeks and 6 weeks.

RESULTS

Tables 1 and 2 show the characteristics of the study population. 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 -0.88, 95%CI of -1.263 and -0.499) 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 -1.13, 95% CI of -1.625 and -0.64) and p value <0.05), between group 2 and 3 (mean difference of -0.98 and 95% CI of -1.48 and -0.49, and 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.

Table 1: Mean Age of the different study groups

	N	Mean	SD	Min.	Max.
Group 1	15	28.40	6.759	20	38
Group 2	15	29.53	6.300	20	39
Group 3	15	28.07	6.902	20	39

Table 2: Gender distribution of the study groups

	Gender		Total
	Male	Female	
Group 1	7	8	15
	46.7%	53.3%	100.0%
Group 2	8	7	15
	53.3%	46.7%	100.0%
Group 3	8	7	15
	53.3%	46.7%	100.0%
Total	23	22	45
	51.1%	48.9%	100.0%

Table 3 Descriptive statistics for Plaque index

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
Baseline	Group1	15	2.9100	.55182	.14248	2.6044	3.2156	2.00	3.50
	Group 2	15	3.0933	.45429	.11730	2.8418	3.3449	2.00	3.50
	Group 3	15	2.9213	.43035	.11111	2.6830	3.1597	2.00	3.50
	Total	45	2.9749	.47820	.07129	2.8312	3.1186	2.00	3.50
Fourth week	Group1	15	1.8193	.55208	.14255	1.5136	2.1251	1.00	2.50
	Group 2	15	1.5953	.35124	.09069	1.4008	1.7898	1.30	2.33
	Group 3	15	2.4767	.31468	.08125	2.3024	2.6509	2.00	3.00
	Total	45	1.9638	.55750	.08311	1.7963	2.1313	1.00	3.00
Sixth week	Group1	15	1.8547	.50347	.13000	1.5759	2.1335	1.00	2.50
	Group 2	15	.7207	.38190	.09861	.5092	.9322	.33	1.33
	Group 3	15	1.7100	.68884	.17786	1.3285	2.0915	1.00	3.50
	Total	45	1.4284	.73333	.10932	1.2081	1.6488	.33	3.50

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Table 4: Descriptive Statistics for Gingival Index									
						95% Confidence Interval for Mean			
		N	Mean	Std. Deviation	Std. Error	Lower Bound	Upper Bound	Minimum	Maximum
Baseline	Group1	15	2.5433	.58836	.15191	2.2175	2.8692	2.00	3.50
	Group2	15	2.5433	.58836	.15191	2.2175	2.8692	2.00	3.50
	Group3	15	2.5540	.58667	.15148	2.2291	2.8789	1.33	3.50
	Total	45	2.5469	.57431	.08561	2.3743	2.7194	1.33	3.50
4th week	Group1	15	1.3547	.33261	.08588	1.1705	1.5389	1.00	2.00
	Group2	15	1.2880	.47745	.12328	1.0236	1.5524	.00	2.00
	Group3	15	2.0540	.49918	.12889	1.7776	2.3304	1.33	3.00
	Total	45	1.5656	.55657	.08297	1.3983	1.7328	.00	3.00
6th week	Group1	15	.9813	.45104	.11646	.7316	1.2311	.00	1.50
	Group2	15	.9813	.45104	.11646	.7316	1.2311	.00	1.50
	Group3	15	1.1533	.71196	.18383	.7591	1.5476	.33	2.50
	Total	45	1.0387	.54540	.08130	.8748	1.2025	.00	2.50

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 and 6).

Table 5: Chi-square test use to compare different intervals at different groups

Visit	Group	BOP		Total	$\chi 2$ value	'p' value
		Absent	Present			
Baseline	Group 1	0	15	15	2.045	0.360
		0%	100.0%	100.0%		
	Group 2	0	15	15		
		0%	100.0%	100.0%		
	Group 3	1	14	15		
		6.7%	93.3%	100.0%		
4th Week	Group 1	7	8	15	1.275	0.529
		46.7%	53.3%	100.0%		
	Group 2	9	6	15		
		60.0%	40.0%	100.0%		
	Group 3	10	5	15		
		66.7%	33.3%	100.0%		
6th Week	Group 1	11	4	15	0.241	0.887
		73.3%	26.7%	100.0%		
	Group 2	12	3	15		
		80.0%	20.0%	100.0%		
	Group 3	11	4	15		
		73.3%	26.7%	100.0%		

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Table 6: Chi-square test use to compare different groups at different intervals

Group	Visit	BOP		Total	χ2 value	'p' value
		Absent	Present			
Group 1	Baseline	0	15	15	17.222	<0.001
		0%	100.0%	100.0%		
	4th Week	7	8	15		
		46.7%	53.3%	100.0%		
	6th Week	11	4	15		
		73.3%	26.7%	100.0%		
Group 2	Baseline	0	15	15	20.893	<0.001
		0%	100.0%	100.0%		
	4th Week	9	6	15		
		60.0%	40.0%	100.0%		
	6th Week	12	3	15		
		80.0%	20.0%	100.0%		
Group 3	Baseline	1	14	15	16.186	<0.001
		6.7%	93.3%	100.0%		
	4th Week	10	5	15		
		66.7%	33.3%	100.0%		
	6th Week	11	4	15		
		73.3%	26.7%	100.0%		

DISCUSSION

Aloe vera is a natural product contained in herbal dentifrices with commercial appeal on the control of plaque and gingivitis. Despite its free commercial use, this phytotherapeutic agent does not have sufficient data to support its anti-gingivitis and anti-plaque activity [3].

The present randomized controlled double blind clinical study was conducted to compare the clinical efficacy of commercially available dentifrice viz Aloe Vera, Aloe Vera with scaling and scaling alone.

45 subjects were recruited in this present study. The test dentifrice had a good acceptance and did not show adverse effects, such as formation of abscess and ulcerations or allergic reactions. Only one subject in the test group reported unpleasant taste, but he did not drop out the clinical trial.

A study assessed the inhibitory activity of Aloe vera gel on some clinically isolated cariogenic and periodontopathic bacteria. *S. mutans* was the species most sensitive to Aloe vera gel with a MIC of 12.5µg/ml, while *A. actinomycetemcomitans*, *P. gingivalis*, and *B. fragilis* were less sensitive, with a MIC of 25-50 µg/ml ($P < 0.01$). Based on previous studies it was concluded that Aloe vera gel at optimum concentration could be used as an antiseptic for prevention of dental caries and periodontal diseases [4].

Previous studies conducted concluded that a higher concentration of *Aloe vera* (50%) had a better effect as a phytotherapeutic agent when compared to our findings. Although the manufacturer does not inform the concentration of *Aloe vera* in the product used in the present study, the percentage of therapeutic agent in a dentifrice usually ranges from 0.4% to 1.0% of the total formulation, which was probably the concentration used in our study and could explain those results [5].

Furthermore, in a previous study, a mouth rinse containing only Aloe vera as the active agent, showed a favourable action without interference of other components. The test dentifrice used in the present trial contains other agents that can promote a moderate anti-plaque effect, such as menthol and sodium lauryl sulphate [5], since the last two components are also present in the patient's regular dentifrices. We concluded that the herbal agent was effective responsible for the improvement in PI scores in group 2 and 3.

Participants in clinical trials may experience some improvement associated not specifically to the therapeutic properties of the test agent but rather related to a behaviour change - *Hawthorne* effect. Another important factor is the *Novelty* effect, which is the motivation of oral hygiene practice by the use of a new substance [6].

Aloe Vera mouthwash can be an effective anti-plaque agent and with its appropriate taste and shelf life can be an affordable substitute for chlorhexidine.[7] Aloe Vera had a significant anti-inflammatory property. Thus, it can be used as an adjunct to mechanical therapy for treating plaque-induced gingivitis [8].

Another experimental gingivitis study reported that the effect of three dentifrices containing triclosan and various additives. Results showed that both the Aloe Vera–containing toothpaste and the toothpaste containing triclosan showed significant improvement over the placebo group. There was no significant difference between the aloe vera–containing toothpaste and the toothpaste containing triclosan in the reduction of PI and GI as well as in the reduction of microbial counts [9,10].

A previous study showed that healing is better and wound tensile strength is increased after its application on wounds [12]. Authors have also used 70% Aloe Vera gel for recurrent aphthous ulcers and lichen planus, which showed that healing, was better and faster.[12] Aloe Vera has also been used for the treatment of radiation ulceration of mucous membrane in the mouth [13].

Another study have used Aloe vera for the gingivectomy sites and showed that healing was better and fast [14]. there was no discomfort, hypersensitivity or abnormal tissue reactions observed in the present study. Hence, subgingival administration of Aloe vera gel results in improvement of periodontal condition. Aloe Vera can be used as local drug delivery systems [15].

The aloe vera gel contains various carbohydrate polymers, notably either glucomannans or peptic acid, along with a wide range of other organic and inorganic components. Treatment of inflammation is still the key factor for most types of healing, and immunomodulatory properties of the gel polysaccharides, especially the acetylated mannans from aloe vera, seem to play a key role. Anti-diabetic, anticancer, and antibiotic activities of aloe vera have also been reported, indicating wider use of this gel [14, 15].

Studies conducted earlier have identified an anti-inflammatory agent as C-glucosyl chromone from Aloe barbadensis. Aloe vera is known to contain several active ingredients, including a carboxypeptidase that inactivates bradykinin in vitro, salicylates, and a substance that inhibits thromboxane formation [15].

Another suggested that the treating with aloe vera extract has also resulted in a significant increase in reduced glutathione, superoxide dismutase, catalase, glutathione peroxidase, and glutathione S-transferase in the liver and kidney of diabetic rats, showing the antioxidant property of aloe vera gel extract [16,17].

Authors have also reported that aloe vera leaf pulp extract was effective in reducing blood sugar, suggesting that it might be useful in scavenging of free radicals. It was reported that treatment with aloe vera increased antioxidant enzymes and significantly reduced lipid peroxidation products in streptozotocin-induced diabetic rats, showing the relationship between antioxidant activity and the onset of diabetes [18].

CONCULSION

Within the limits of the study, it can be concluded that Aloe Vera can be used as an adjunct to scaling (Oral prophylaxis) to obtain improvement in clinical parameters (PI, GI, BOP).

However due to the limited sample size and short duration of assessment, long term prospective studies was required to evaluate the numerous clinical applications of Aloe Vera.

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