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CLINICAL OUTCOMES USING PREBIOTIC AND PROBIOTIC LOZENGES IN NON-SURGICAL MANAGEMENT OF CHRONIC PERIODONTITIS PATIENTS

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ABSTRACT

Non-surgical therapy primarily reduces the number of pathogens. However, recolonization occurs rapidly. In this context, the administration of beneficial bacteria in the form of prebiotic & probiotics lozenges has emerged as a promising therapeutic option in the prevention and treatment of periodontal diseases. The present study aimed to evaluate the efficacy of combined prebiotic and probiotic lozenges as an adjunct to non-surgical therapy in chronic periodontitis patients and to correlate the clinical parameters between both the groups. 30 systemically healthy patients aged 20-55 years diagnosed with chronic periodontitis patients were randomly recruited. Test group (15 subjects) received non-surgical therapy and pre & probiotic lozenges twice daily for 21 days, whereas the control group (15 subjects) received only non-surgical therapy. Clinical parameters were recorded at base line (BI), 3 and 6 weeks follow up period. Repeated measures anova analysis was used for measuring test and control group, independent sample t test was used for measuring between both groups. Both the groups demonstrated significant reduction ($p < 0.05$) in clinical parameters from baseline to 3 weeks. BI slightly increased from 3 weeks to 6 weeks and all the other clinical parameters remained same from 3 weeks to 6 weeks in both the groups. No statistically significant difference was observed when compared between test and control groups from 3 weeks and 6 weeks. Within the limitations of the study it can be concluded that Combined use of prebiotic and probiotic lozenges as an adjunct to scaling and root planing (SRP) demonstrated significant improvement in clinical parameters when compared to mechanical debridement alone.

KEY WORDS: ***Scaling and root planing; chronic generalized periodontitis; Lactobacillus Sporogenes; Streptococcus faecalis; Bacillus mesentericus.***

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INTRODUCTION

It is well established that periodontal destruction is substantially mediated by the host and driven by bacterial challenge. Presence of pathogenic bacteria and absence of so-called "beneficial bacteria" and increased susceptibility of host are main aetiological factors of periodontal disease. Conventional treatment modalities include non-surgical management which emphasizes on mechanical debridement that is often accompanied by antibiotics, antimicrobials via local drug delivery which aim to reduce the pathogenic load. Due to emergence of antibiotic resistance and frequent recolonization with pathogenic bacteria, probiotics has evolved as adjunct to non-surgical periodontal therapy[1-3]. The term probiotic, meaning "for life," is derived from Greek and first used by Lilly and Stillwell in 1965[4]. According to WHO/ FAO 2012, probiotics are live micro-organisms which, when administered in adequate amounts, confer health benefits on the host[5]. Gibson and Roberfroid introduced the term 'prebiotic' and defined it as non-digestible oligosaccharides that stimulate the growth and/or activity of probiotics. Example: fructo - oligosaccharides, gluco - oligosaccharides and insulin. Traditionally dietary sources of prebiotics include soyabeans, raw oats, unrefined wheat, barley and yacon. The most commonly used probiotics are Lactobacillus spp. and Bifidobacterium spp [6-7]. The term synbiotic is used when a product contains both probiotics and prebiotics[8].Evidence on administration of probiotic lozenges alone adjunct to SRP has shown reduction in all clinical parameters of chronic periodontitis patients[9-13]. However, to the author's knowledge there is no literature evidence on the combined use of pro and prebiotics lozenges as an adjunct to SRP in chronic periodontitis patients. Hence, the aim of the present study is to determine the effects of combined pro & prebiotics lozenges as an adjunct to SRP during and after non-surgical therapy.

MATERIALS AND METHODS

Study design and subjects

The present study was a case -control clinical trial performed in Department of Periodontology, SRM Dental College from July 2015 to June 2016.The patients were explained about the study protocols and treatment outcomes. A written informed consent was obtained from all the patients and approved by the institutional and scientific review board of SRM University. 30 systemically healthy chronic periodontitis patients who reported to the outpatient Department of Periodontology, SRM Dental College were selected. Sample size was calculated based on the results of a study done by Dhawan et al 2013[7]. To obtain a power of 90% with an α-error of 0.005, the current study required a sample size of 30. Male and female patients aged 30-55 years were included in the study. Patients diagnosed with generalized chronic periodontitis with probing pocket depth of 5-6 mm were included in the study. Exclusion criteria includes patients with systemic diseases, smokers, alcohol consumers and pregnancy, lactating mothers. Subjects who used antibiotics within 3 months of enrolment, drug history of Dilantin sodium, nifedipine, amlodipine that is associated with gingival enlargement and patients who had undergone periodontal surgeries before 1 year were also excluded from the study. Subjects who fulfilled the inclusion criteria were selected by a convenience sampling and they were randomly allocated into test and control group. Group 1(Test group) consisting of 15 subjects received prebiotic and probiotic lozenges for 3 weeks after SRP and Group 2(control group) consisting of 15 patients received SRP alone.

Probiotic product

The study product Bifilac Probiotic and Prebiotic lozenges (Allianz biosciences private ltd., Chennai, India) containing Lactobacillus sporogens 50 million, Streptococcus faecalis T110 JPC 30 million, Clostridium butyrium TOA 2 million, and Bacillus mesentericus TO-A JPC 1 million. Subjects in test group consumed two pre & probiotic Lozenges twice daily after food for 3 weeks. They were also instructed not to change their oral hygiene regimen.

Clinical examination

Each patient was assigned a customized case sheet and the clinical parameters were recorded. The clinical parameters were recorded at baseline, 3 weeks and 6 weeks. Full mouth plaque index (FMPI), full mouth gingival index (FMGI), full mouth bleeding score (FMBI), probing sulcus depth (PPD), clinical attachment levels (CAL) were recorded at each visit. FMPI was assessed using Sillness and Loe (1964). FMGI was assessed using the Loe & Sillness (1963). PPD & CAL was assessed by gently inserting a 15 mm calibrated plastic periodontal probe (Hu – Freidy®) by measuring from gingival margin till the base of pocket, and CAL was measured from the CEJ to the base of the pocket on the mesio-buccal, mid-buccal, disto-buccal and mesio-lingual, mid-lingual, disto-lingual aspects.

STATISTICAL ANALYSIS

The statistical analysis for all the parameters were performed by using descriptive statistics, independent sample t test and repeated measures ANOVA. The Repeated Measures Anova was used to evaluate the differences in time within groups, and independent sample t test was used to evaluate intergroup comparisons. Data was analysed using a statistical software program SPSS version 16.

RESULTS

30 systemically healthy chronic periodontitis patients with a mean age of 42.5 years were selected for the study and treated by two different treatment protocols. Control sites (n=15) underwent SRP alone and the test sites (n=15) were treated with prebiotic and probiotic lozenges after SRP. Clinical parameters namely full mouth plaque scores, full mouth gingival index, full mouth bleeding score, probing sulcus depth, clinical attachment levels were recorded at baseline, 3 weeks and 6 weeks respectively. Clinical parameter changes from baseline to 6 weeks were statistically significant within both groups (p = 0.05) except for CAL which was not statistically significant (p =1.0) (Table 1, 2).Changes

in clinical parameters from baseline to 6 weeks when compared between test and control groups showed no significant difference. (Table 3). Clinical parameter changes from baseline to 3 weeks were statistically significant within both groups, but from 3 weeks to 6 weeks there was no statistically significant difference, except for bleeding index where there was increase within groups. (Graph 1, 2, 3)

Table 1
Changes in clinical parameters within test group

Clinical parameters	Test group			
	Base line	3 weeks	6 weeks	Change from Baseline to 6 weeks P - value
	Mean ± SD	Mean ± SD	Mean ± SD	
Probing Depth	3.93 ± 0.91	3.04 ± 1.17	3.04 ± 1.17	.002*
Clinical Attachment Level	4.94 ± 1.05	3.52 ± 1.71	3.52 ± 1.71	.002*
Bleeding Index	1.56 ± 0.72	0.21 ± 0.41	0.46 ± 0.44	.000*
Plaque Index	1.80 ± 0.84	0.76 ± 0.55	0.92 ± 0.63	.000*
Gingival Index	1.20 ±0.75	0.46 ± 0.48	0.53 ± 0.44	.002*

* The mean difference is significant at p = 0.05.

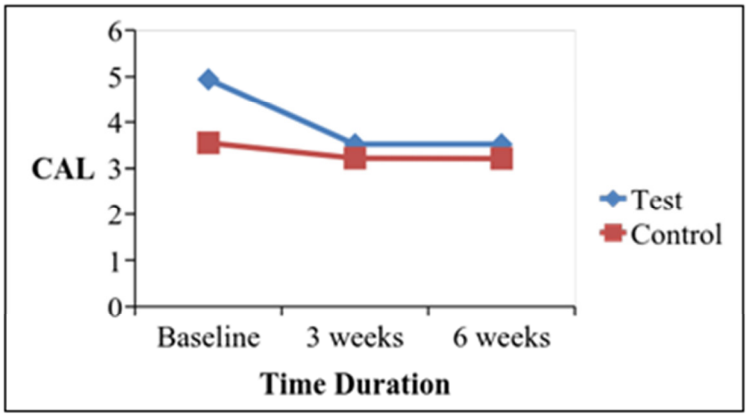
Table 2
Changes in clinical parameters within control group

Clinical parameters	Control group			
	Base line	3 weeks	6 weeks	Change from Base line to 6 weeks
	Mean ± SD	Mean ± SD	Mean ± SD	P – value
Probing Depth	3.81 ± 0.83	2.78 ± 0.89	2.79 ± 0.89	.000*
Clinical Attachment Level	3.55 ± 1.82	3.22 ± 1.57	3.21 ± 1.56	1.0
Bleeding Index	1.10 ± 0.32	0.31 ± 0.46	0.65 ± 0.47	.002*
Plaque Index	1.81 ± 0.30	0.80 ± 0.38	0.90 ± 0.51	.000*
Gingival Index	1.76 ± 0.25	0.60 ± 0.50	0.66 ± 0.48	.000*

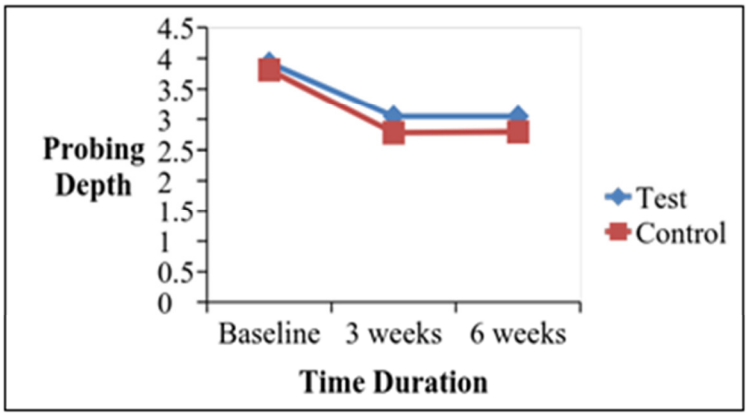
*The mean difference is significant at p = 0.05.

Table 3
Comparison of clinical parameters between test and control

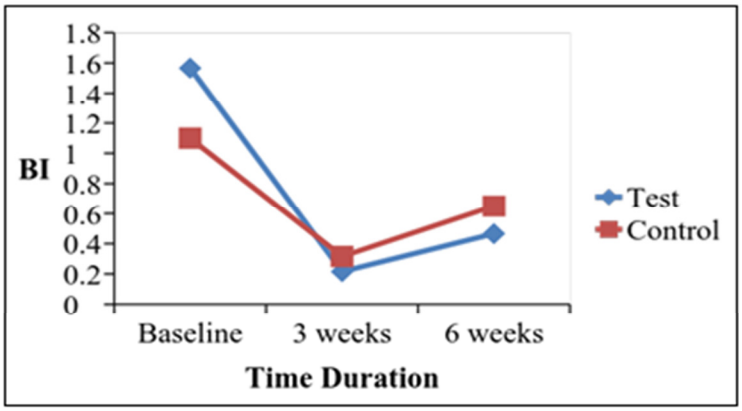
Clinical parameters	Test group	Control group	
	6 weeks	6 weeks	
	Mean ± SD	Mean ± SD	P
Probing Depth	3.04 ± 1.17	2.7±0.89	0.51
Clinical Attachment Level	3.52 ± 1.71	3.21± 1.56	0.61
Bleeding Index	0.46 ±0.44	0.65 ± 0.47	0.28
Plaque Index	0.92 ± 0.63	0.90 ± 0.51	0.92
Gingival Index	0.53 ±0.44	0.66 ± 0.48	0.43



Graph1
Depicting changes in clinical attachment level between test and control



Graph2
Depicting changes in probing pocket depth between test and control



Graph3
Depicting changes in bleeding index between test and control

DISCUSSION

The present study has made a novel attempt to determine the combined effects of pro & prebiotics lozenges in the treatment of chronic periodontitis. None of the subjects reported adverse effects during the administration of probiotics. The clinical parameters (plaque index, gingival index, bleeding index, probing depth, clinical attachment level) in the present study were recorded at baseline, 3 weeks and 6 weeks. The current study showed a statistically significant reduction in plaque index in both the groups at 3 weeks and 6 weeks as compared to baseline ($p < 0.05$).This was in accordance to studies done by Vivekananda et.al 2010, Shinmauchi et.al 2008 ,who demonstrated a reduction in amount of plaque index as compared to baseline values for the probiotic group. This plaque inhibitory effect could be attributed to the antimicrobial effects of probiotics which prevents the adherence of bacteria and modifies the protein composition of the salivary pellicle by binding and degradation of salivary proteins[8, 13].Polansky et al., 1952 demonstrated the phenomenon that probiotic strains such as lactobacillus acidophilus may inhibit the *invitro* growth of Aggregatibacter actinomycetemcomitans, Porphyromonas gingivalis, Porphyromonas intermedia which are the potent microorganisms responsible for periodontal destruction[20]. Similarly, Toiviainen A et al, 2015 have shown reduction in plaque index scores following oral administration of probiotic lozenges[10].In the present study, the gingival index scores and bleeding on probing scores showed decrease in both the groups at 3 weeks and 6 weeks when compared to baseline ($p < 0.05$).This was in accordance to studies done by Vivekananda set.al 2010, who demonstrated a reduction in amount of gingival index as compared to baseline values for the probiotic group[8].Similarly, Krasse et al, 2006 showed reduced gingival bleeding and gingival inflammation following oral administration of lactobacilli reuteri lozenges[12]. Teughels et al, 2013 showed reduction in bleeding scores following oral administration of probiotic lozenges. Anti-inflammatory effect of probiotics could be attributed due to the reduction in pro inflammatory cytokines such IL-1beta, TNF- alpha, IL-8[14-16].In the present study, the periodontal parameters (PPD, CAL) showed reduction in both groups at 3 weeks and 6 weeks when compared to baseline ($p < 0.05$). This was attributed by the effect of probiotic microorganisms which not only act on microbiota but also protect the oral cavity through the promotion of a beneficial host response. They exert effects either by modulating the immunological parameters, epithelial permeability, and

bacterial translocation, or by providing bioactive or regulatory metabolites. The current evidence shows that the destruction of the periodontium is substantially mediated by host and driven by bacterial challenge. Therefore, probiotics might not only suppress the emergence of endogenous pathogens or prevent the super-infection with exogenous pathogens but also protect the oral cavity through the promotion of a beneficial host response. Probiotic bacteria or their products (e.g. metabolites, cell wall components, and DNA) can be recognized by host cells such as epithelial cells and immune cells. Increased phagocytic capacity of macrophages when challenged with L. acidophilus and Lactobacillus casei has been reported. It is known that probiotics can regulate the expression of phagocytosis receptors in the neutrophils of healthy individuals and enhance natural killer cell activity. A more in-depth study of the molecular mechanisms has revealed that probiotic species could effectively reduce the levels of periodontal inflammation associated molecules, such as prostaglandin E_2 and interferon-γ, and weaken matrix metalloproteinase activities in saliva[17-19].In the present study, the beneficial impact of probiotic bacteria is well established by significant reduction observed in Probiotic group as compared to control group. The observed improvement in clinical parameters may be attributed to the reduced levels of cariogenic as well as periodontal pathogens and effective colonization of the probiotic bacteria within the oral cavity. Residence time of probiotics in the oral cavity after treatment withdrawal is not yet known[17]. The results do not suggest that a permanent installation can take place in persons with established microflora. But the mechanism of action of probiotics suggests that they do not permanently colonize their host; even repeated daily use of probiotic over a long period of time will support its increased level in the oral cavity. Since it seems unlikely that probiotics have any significant residual effect after discontinuation of intake, daily intake seems to be a prerequisite for potential action. The present study had the following limitations such as short term follow up and limited number of samples. Microbiological analysis would have added value to the results of the present study.

CONCLUSION

The present study was a first attempt at evaluating the combined efficacy of pre and probiotic lozenges adjunct to SRP. Probiotics used for the management of periodontal disease is the idea of replacing harmful microorganisms with beneficial bacteria or genetically modified bacteria is very attractive. Much more scientific developments are needed to have a better understanding of these organisms in order to broaden their potential applications. Thus, within the limits of the present study it can be demonstrated that the adjunctive use of probiotic & prebiotic lozenges along with scaling and root planing has led to significantly better clinical outcome compared to scaling & root planing alone. Further studies on larger sample sizes with longer recall periods are suggested for evaluating the therapeutic effects of probiotics.

CONFLICT OF INTEREST

Conflict of interest declared none.

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