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Original Article

To assess the efficacy of *Bacillus clausii* UBB-07 2 Billion spores on gingivitis: A randomized control trial

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Abstract

Background and Objectives: The aim of this study was to evaluate the effects of probiotic *Bacillus clausii* UBBC-07 2 Billion spores alone and in combination with scaling in a randomized, placebo-controlled clinical trial of volunteers with chronic generalized gingivitis.

Materials and Methods: Thirty otherwise systemically healthy, chronic generalized gingivitis subjects (both males and females, aged between 18 and 40 years) were included. Selected subjects were randomly divided into two groups. The study period was 7 days. "Split-mouth" design was used for scaling, which was performed on day 0; two quadrants (either right or left) were treated with scaling whereas the remaining two quadrants were left untreated. Participants in the test group received probiotics, *B. clausii* UBB-07-2 Billion spores as mouth rinse twice daily for 7 days and in the control group received placebo rinse twice daily for 7 days. Further treatment for the subjects was carried out after 7 days. Statistical analysis was done for comparisons of clinical parameters (plaque index [PI], gingival index [GI], and sulcus bleeding index [SBI]). A $P < 0.05$ was considered statistically significant. Assessments were made on day 0 before scaling treatment, on day 0 before administration of the mouth rinse, and on day 7.

Results: At day 7, the PI, GI, and SBI were significantly reduced by all treatment modalities. When ranked, the amount of PI, GI, and SBI reduction by the different treatments were scaling with probiotics, probiotics, scaling with placebo, placebo all differences were statistically significant.

Conclusion: The present randomized double-blind controlled trial confirms the plaque inhibition effects of *B. clausii* UBB-07-2 Billion spores probiotics. *B. clausii* UBB-07-2 Billion spores probiotic can be recommended alone and in combination with scaling and also during the maintenance phase of periodontal treatment.

Keywords: *Bacillus clausii*, chronic generalized gingivitis, placebo, probiotics, scaling, spore

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INTRODUCTION

Probiotics can be defined as living microbes or as food ingredients containtabeleing living microbes that beneficially influence the health of the host when used in adequate numbers.[1] As validated by the International Scientific Association for probiotics and prebiotics, "live microorganisms, which when administered in adequate amounts, confer beneficial effect on the health of the host."

The idea of probiotics came to existence in the first decade of 1900s when the Ukranian bacteriologist and Nobel Laureate Metchnikof (1908) were studying the flora of

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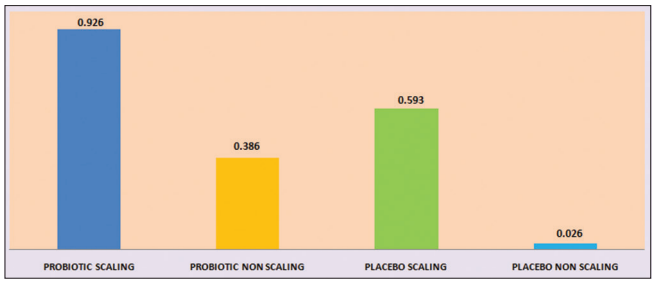
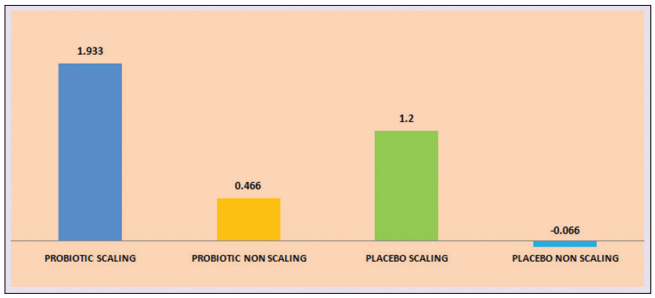
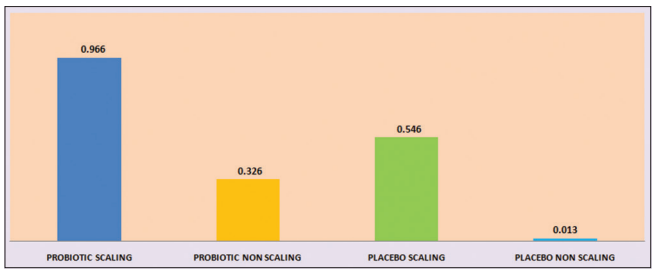


Graph 1: Mean plaque index



Graph 2: Mean sulcus bleeding index



Graph 3: Mean gingival index

human intestine and developed a theory that senility in humans is caused by poisoning of body by the products of some of these bacteria. To prevent the multiplication of these organisms, they proposed a diet containing milk fermented by lactobacilli, which produces large amounts of lactic acid that could increase the life span of humans. The notion of probiotics was thus born and a new discipline of bacteriology was opened.[1]

Lilley and Stillwell (1965) introduced the term probiotics. Hull, in 1984, discovered the first probiotic species, *Lactobacillus acidophilus*. Later, in 1991, Holcombh identified *Bifidobacterium bifidum*. The WHO in 1994 described the probiotics as the next most important in immune defense system following antibiotic resistance. This prevalence leads the way for a new abstraction of probiotics in medicine and dentistry.[2]

Bacillus species which are spore-forming bacteria have been used as probiotics for the last five decades. The edge of spore-forming probiotics over nonspore formers such as *Lactobacillus* spp. is that they can be stored at room temperature without any loss of viability and are heat stable. Spore-forming bacteria are also resistant to acidic conditions. The immune response can be modulated by a probiotic *Bacillus clausii*.[3,4]

B. clausii is currently being studied in respiratory infections, oral candidiasis, and aphthous ulcer. The effect of *B. clausii* on the periodontium is unknown. Therefore, the aim of the study was to assess the efficacy of *B. clausii* UBB-07-2 Billion spores on gingivitis.

MATERIALS AND METHODS

This was a randomized, placebo-controlled, split-mouth designed clinical study to evaluate the effect of probiotic *B. clausii* UBB-07-2 Billion spores with and without scaling on the clinical parameters.

Patients of both sexes within the age limit of 18–40 years were eligible for inclusion. Patients diagnosed as suffering from chronic generalized gingivitis with 30% sites with bleeding on probing and right-handed subjects were included. Apart from having chronic generalized gingivitis, the patients were in good general health. No patient had ongoing antibiotic treatment or any systemic disease. Patients who were pregnant, lactating, smokers, alcoholic, or who had undergone any periodontal therapy within 6 months before the start of the study were excluded from the study. Informed consent was obtained in writing from all the subjects included in the study.

All subjects were assigned to one of the two groups (probiotics group or placebo group) using randomization (chit method) as shown in consort chart [Figure 1]. Probiotics were procured from Karnataka Antibiotics and Pharmaceuticals Ltd., Bangalore. Clinical parameters recorded were plaque index (PI), gingival index (GI), and sulcus bleeding index (SBI) and were recorded at baseline (day 0) and on day 7. The clinical parameters recorded were PI, GI, and SBI. All parameters were assessed by a single clinical investigator. Split-mouth scaling in all patients was achieved by treating two quadrants with scaling on day 0 while two quadrants were left untreated. Scaling of other two quadrants was completed after completion of the study. Participants in the test group received probiotics, *B. clausii* UBB-07-2 Billion spores as mouth rinse twice daily for 7 days and in the control group received placebo rinse twice daily for 7 days. The patients were instructed to perform regular oral hygiene habits, i.e., twice-daily brushing for a minimum of 2 min, followed by mouth rinse for 7 days. All clinical and data collected were subjected to statistical analysis.

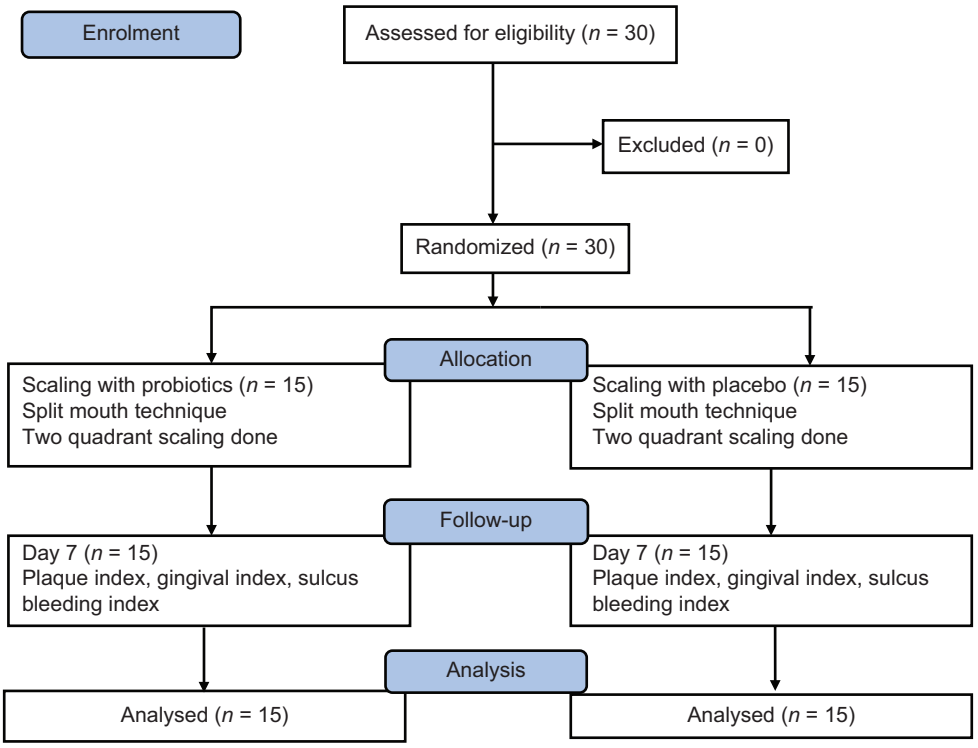


Figure 1: Consort chart

Table 1: One way ANOVA

		n	Mean	Std. deviation	*F*	df	*P*
PI	Probiotic scaling	15	0.926	0.186	123.718	59	<0.001
	Probiotic non scaling	15	0.386	0.124			
	Placebo scaling	15	0.593	0.127			
	Placebo non scaling	15	0.026	0.045			
SBI	Probiotic scaling	15	1.933	0.258	79.761	59	<0.001
	Probiotic non scaling	15	0.466	0.516			
	Placebo scaling	15	1.200	0.414			
	Placebo non scaling	15	-0.066	0.258			
GI	Probiotic scaling	15	0.966	0.134	187.933	59	<0.001
	Probiotic non scaling	15	0.326	0.045			
	Placebo scaling	15	0.546	0.155			
	Placebo non scaling	15	0.013	0.083			

*$P<0.05$ is considered statistically significant. Mean PI, SBI, and GI between the groups using one-way ANOVA. PI: Plaque index, GI: Gingival index, SBI: Sulcus bleeding index

RESULTS

All subjects completed the 7-day study period. There were no significant differences in the clinical parameters between the Probiotic and placebo groups on day 0. A $P < 0.05$ was considered statistically significant. The power size was 0.8. The effect size calculated was 1.1.

The mean difference in PI score of probiotic scaling group was 0.926 ± 0.186, of probiotic group was 0.386 ± 0.124, of placebo scaling group was 0.593 ± 0.127, and of placebo without scaling group was 0.026 ± 0.045. There were statistically significant differences in PI score among four groups (i.e., $P < 0.001$) [Graph 1 and Tables 1 and 2].

The mean difference in SBI score of probiotic scaling group was 1.933 ± 0.258, of probiotic group was 0.466 ± 0.516, of placebo scaling group was 1.200 ± 0.414, and of placebo without scaling group was −0.066 ± 0.258. There were statistically significant differences in SBI score among four groups (i.e., $P < 0.001$). [Graph 2 and Tables 1 and 2].

The mean difference in GI score of probiotic scaling group was 0.966 ± 0.134, of probiotic group was 0.326 ± 0.045, of placebo scaling group was 0.542 ± 0.155, and of placebo without scaling group was 0.013 ± 0.083. There were statistically significant differences in GI score among four groups (i.e., $P < 0.001$) [Graph 3 and Tables 1 and 2].

Scheffe *post hoc* test was used for pairwise comparisons; there was a statistically significant difference in mean PI, SBI, and GI score between each pair.

Within both the probiotic and the placebo groups, with PI, GI, and SBI, the reduction was highly significant with treatment. The maximum reduction of PI, GI, and SBI was obtained for the combination of scaling and probiotics, which was statistically significant when compared to all other treatment modalities. In the untreated quadrants, probiotics was significantly better than the placebo.

Table 2: Scheffe *post hoc* test

Dependent variable	Reference Group	Comparison group	*P*
PI	Probiotic scaling	Probiotic non scaling	<0.001
		Placebo scaling	<0.001
		Placebo non scaling	<0.001
	Probiotic non scaling	Placebo scaling	0.001
		Placebo non scaling	<0.001
	Placebo scaling	Placebo non scaling	<0.001
SBI	Probiotic scaling	Probiotic non scaling	<0.001
		Placebo scaling	<0.001
		Placebo non scaling	<0.001
	Probiotic non scaling	Placebo scaling	0.004
		Placebo non scaling	<0.001
	Placebo scaling	Placebo non scaling	<0.001
GI	Probiotic scaling	Probiotic non scaling	<0.001
		Placebo scaling	<0.001
		Placebo non scaling	<0.001
	Probiotic non scaling	Placebo scaling	<0.001
		Placebo non scaling	<0.001
	Placebo scaling	Placebo non scaling	<0.001

*$P<0.05$ is considered statistically significant. Pairwise comparison between the subgroups using Scheffe *post hoc* test

DISCUSSION

An initial attempt has been made in this randomized, double-blind clinical trial to evaluate and compare the benefits of the probiotic alone and scaling with probiotics in the treatment of chronic generalized gingivitis.

In both the probiotics and the placebo groups, PI, GI, and SBI were significantly reduced within each treatment group over 7 days except for placebo group. In the probiotic group, the combination of scaling and probiotics demonstrated a significant reduction of PI, GI, and SBI when compared to scaling and probiotic effects individually; thus, the plaque reduction brought about by scaling was enhanced by the use of probiotics.

In oral cavity, probiotics can create a biofilm, acting as a protective lining for oral tissues against oral diseases.[5]

Lactobacillus and *Bifidobacterium* spp. have earned many health claims, including the potential to modulate host physiology via direct and indirect means.[6] In a recent study, 20 healthy European subjects were orally administered with Enterogermina-containing spores of four strains of *B. clausii*, which could survive transit through the human gastrointestinal tract during which germination; out-growth and multiplication could happen.[7] The available data from these studies have presented the beneficial effects of different strains of *Bacillus* spp. for human health. For example, several researchers have recognized the preventive role of *Bacillus* probiotic in gut physiology impairment condition.[8]

The probiotic *B. clausii* strain protected vero and Caco-2 cell from the cytotoxic effect of *Clostridium difficile* and *B. cereus* toxins.[9]

Enterogermina contains spores of four strains of *B. clausii*, which are resistant toward tetracycline and chloramphenicol. Suspension of these spores is used as medical supplement along with antibiotics against infantile diarrhea.[10]

CONCLUSION

The present randomized, double-blind controlled trial confirms the plaque inhibition effects of *B. clausii* UBB-07 2 Billion spores probiotic. *B. clausii* UBB-07 2 Billion spores can be recommended alone and in combination with scaling and also during the maintenance phase of periodontal treatment. Further studies are required in this direction.

From the results obtained, the following conclusions could be drawn from this study:

- Probiotic *B. clausii* UBB-07-2 Billion spores is a promising modality of treatment, offering some benefits over scaling.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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