



Comparative Efficacy of Two Different Probiotic Formulations Containing *Lactobacillus Paraceasi* in Stage I and II Periodontitis - A Clinical Trial.

1. K. Naga sai Likhitha; 2. Dr. Gangolu Meghana (Corresponding Author); 3. Dr. Jaswitha V; 4. Dr. Chaitanya Adurty; 5. K. Akshaya Manasa; 6. Manaswini Mupaneni

1,5,6: Undergraduate student, Sibar institute of dental sciences, Guntur, Andhra pradesh, India.

2,3: Assistant Professor, Department of Periodontics, Sibar institute of dental sciences, Guntur, Andhra pradesh, India.

4: Professor, Department of Periodontics, Sibar institute of dental sciences, Guntur, Andhra pradesh, India.

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ABSTRACT:

Aim and Background: Periodontitis is a highly prevalent inflammatory disease influenced by dysbiosis of the oral microbiota. Probiotics have emerged as a promising adjunct to conventional periodontal therapy. This study compares the clinical efficacy of two probiotic formulations containing *Lactobacillus paraceasi* a tablet and a sachet form as adjuncts to scaling and root planing in patients with Stage I and II periodontitis.

Materials and methods: In this randomized controlled clinical trial, 32 systemically healthy participants aged 21–55 years with Stage I or II periodontitis were randomly allocated into two groups (n = 16 each). Group A received probiotic tablets, while Group B received probiotic sachets for 30 days following oral prophylaxis. Plaque Index (PI), Sulcus Bleeding Index (SBI), and Probing Pocket Depth (PPD) were recorded at baseline and after one month. Intragroup and intergroup comparisons were performed using paired and independent t-tests, respectively.

Results: Both groups showed reductions in clinical parameters after one month. Group A demonstrated statistically significant intragroup improvements in PI, SBI, and PPD ($p < 0.05$). Intergroup comparison at one month revealed significantly greater reductions in PI and SBI in Group A compared to Group B, while the difference in PPD was not significant.

Conclusion: Probiotic tablets containing *Lactobacillus paraceasi* appear to be more effective than sachet formulations as an adjunct to scaling and root planing in improving short-term periodontal clinical outcomes in Stage I and II periodontitis. Larger and long-term studies are warranted.

Introduction

Periodontal disease is one of the most significant oral health conditions contributing to the global burden of chronic disease, with an estimated prevalence of approximately 51% in India.[1] Periodontitis develops as a consequence of untreated gingivitis associated with bacterial plaque accumulation. It is characterized by alterations in the marginal gingiva, bleeding on probing, and irreversible periodontal attachment loss, leading to the formation of periodontal pockets and gingival recession. Progressive bone resorption may further result in tooth mobility and eventual tooth loss. Gingival

inflammation is considered a necessary prerequisite for the subsequent development of periodontitis, which is clinically manifested by attachment loss (CAL), periodontal pocket formation, gingival bleeding, and progressive destruction of the supporting tissues around teeth.[2]

The oral microbiota comprises a complex and diverse community of microorganisms residing within the oral cavity, playing a crucial role in maintaining oral health and homeostasis. These microorganisms exist in a symbiotic relationship with the host immune system, contributing to the modulation of immune responses and



offering protection against pathogenic invasion. However, disruption of this microbial balance, known as dysbiosis, may contribute to the development of common oral diseases such as dental caries and periodontitis.[3]

Probiotics may aid in restoring microbial equilibrium by suppressing the growth of pathogenic bacteria, producing antimicrobial compounds, and competing for adhesion sites on oral tissues. In addition, probiotics have demonstrated the ability to modulate host immune responses, thereby reducing inflammation and enhancing the natural defense mechanisms of the oral cavity.[4]

World Health Organization (WHO) defines probiotics as live cultures of microorganisms that confer a health benefit on the host when administered in adequate amounts.[5] They can be administered either systemically or locally and is a safer alternative as it excludes the disadvantages faced with antibiotics. Clinical studies have reported that probiotic strains, particularly *Lactobacillus* and *Bifidobacterium*, may reduce periodontal pocket depth, gingival inflammation, and plaque accumulation, supporting their potential as a complementary approach in periodontal therapy.[6] Probiotics exhibit generalized mucosal immunity, pro and anti-inflammatory cytokine regulation, antibacterial effect, reduction of Volatile Sulphur compounds (VSC's), T helper cell regulation, tumour cell apoptosis, immune modulatory effect, etc.[7,8]

The present study aims to evaluate the efficacy of probiotics which contains the *Lactobacillus paraceasi* strains in a tablet and powder form, as an adjunct to scaling for a group of patients with stage I or II periodontitis.

Materials and Methods:

The present randomized controlled trial was conducted to evaluate and compare the clinical efficacy of probiotic tablets and probiotic sachets as adjuncts to oral prophylaxis in patients diagnosed with Stage I and II periodontitis. The study was performed in the Department of Periodontics, Sibar Institute of Dental Sciences, Guntur, after obtaining approval from the Institutional Ethical Committee (IEC) with the number (Pr.663/IEC/SIBAR/2025).

Outpatients attending the Department of Periodontics and diagnosed with Stage I or II periodontitis were recruited as the study population. A CONSORT flow diagram [9] depicting participant enrolment and allocation is presented in Fig. 1.

The study included systemically healthy individuals aged between 21 and 40 years who visited the Department of Periodontology and met the inclusion and exclusion criteria. Under inclusion criteria are patients within age group of 21 and 55 years, with presence of at least 20 permanent teeth, probing pocket depth ≤ 5 mm, patients not currently on any systemic medications and patients requiring oral prophylaxis. Under exclusion criteria are patients who smoke or consume alcohol, pregnant or lactating women, presence of systemic disease and patients on routine daily medication.

Sample size estimation was performed using a two-tailed t-test to determine the difference between two independent means. The parameters used were Effect size (d) = 1.0, Alpha error probability (α) = 0.05 with Power ($1-\beta$) = 0.80 and allocation ratio (N_2/N_1) = 1. The required sample size was calculated to be 14 subjects per group (total $n=28$). To compensate for a 20% dropout rate, two additional subjects were included in each group, resulting in a final sample of 16 participants per group with 32 as overall participants.

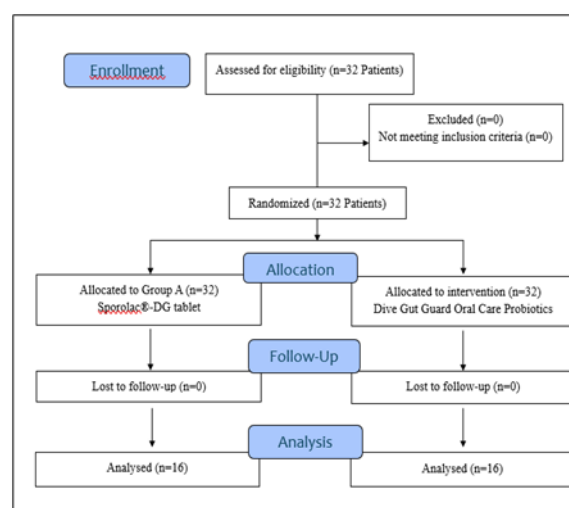


Fig 1: Consolidated Standards of Reporting Trials (CONSORT) flow diagram of the study



At the baseline visit, a comprehensive periodontal examination was carried out, and the clinical indices Plaque Index (PI) by Silness and Loe 1964, Sulcus Bleeding Index (SBI) by Muhlemann and Son 1971 and Probing Pocket Depth (PPD) were recorded for each participant. Full-mouth oral prophylaxis was then performed, followed by personalized oral hygiene instructions.

A total of 32 eligible participants (n=32) were randomly assigned into two equal groups (n=16) using a simple randomization method in sealed envelope technique. Group A comprised of subjects received oral prophylaxis followed by administration of probiotic oro-dental tablets of Sporolac®-DG (fig.2) once daily at night before sleep for a period of 30 days.



Fig 2: Sporolac®-DG Tablets by JB Chemicals & Pharmaceuticals Ltd



Fig 3: Dive Gut Guard oral care powder probiotic

The tablet is advised not to swallow but to place on tongue until it is dissolved. Group B comprised of subjects received oral prophylaxis followed by

administration of probiotic sachets of Dive Gut Guard Oral Care Probiotics (fig.3), taken once daily in 100 ml of water for 30 days. Participants were instructed to follow the respective probiotic regimen assigned to their group for a duration of 30 days. Re-evaluation of all clinical parameters was conducted at the follow-up visit on the 30th day. The total study period was 30 days, including baseline and follow-up assessments.

Results:

Data entries were done in Microsoft Office Excel, and analyses of results were done using Statistical product and service solution (SPSS) version 21 software developed by IBM Corp., Armonk, New York, USA. Descriptive Statistics was used to calculate the means and standard deviation of parameters at baseline, and at 30th days in both groups. paired t-test for intragroup comparison, an independent sample t-test for intergroup comparison, Chi square test for categorical variables was employed. The P value ≤ 0.05 , was considered significant. A total of 19 males (59.4%) and 13 females (40.6%) were included in the study.

Intergroup comparison: An independent sample t-test was performed to compare the baseline and 1month clinical parameters (PI, SBI, and PPD) between the Group A and Group B.

The results showed no statistically significant difference between the two groups at baseline in any of the clinical parameters (table 1, graph 1).

For Plaque Index (PI), the mean score in the Group A was 1.96 ± 0.95 , while in the Group B it was 2.20 ± 0.53 ($t = -0.881$, $p = 0.385$). Similarly, for Sulcus Bleeding Index (SBI), the mean was 3.75 ± 0.44 in the Group A and 3.87 ± 0.61 in the Group B ($t = -0.655$, $p = 0.518$). For Probing Pocket Depth (PPD), the Group A had a mean of 4.37 ± 1.02 , and the Group B had 4.56 ± 0.51 ($t = -0.655$, $p = 0.519$). Hence, both groups were comparable at baseline with no significant difference ($p > 0.05$), indicating homogeneity between the groups before the intervention.

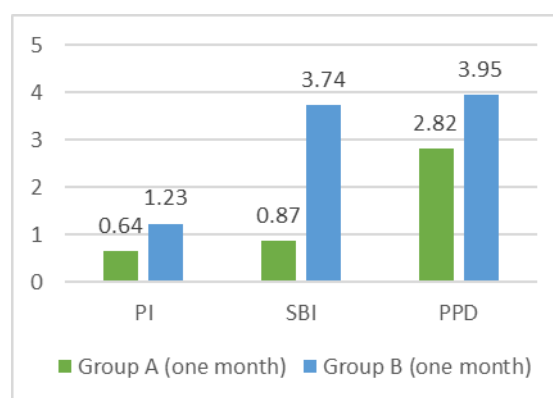


Clinical Indices	Groups (n=14)	Mean± St dev	t Value	p value
Plaque index (PI)	Group A baseline	1.96±0.95	-0.881	0.385
	Group B baseline	2.20±0.53		
	Group A 1 month	0.64±0.36	-4.102	0.002
	Group B 1 month	1.23±0.63		
Sulcus Bleeding index (SBI)	Group A baseline	3.75±0.44	-0.655	0.518
	Group B baseline	3.87±0.61		
	Group A 1 month	0.87±0.26	6.872	0.003
	Group B 1 month	3.74±0.73		
Probing pocket depth (PPD)	Group A baseline	4.37±1.02	-0.655	0.519
	Group B baseline	4.56±0.51		
	Group A 1 month	2.82±0.84	-4.134	0.019
	Group B 1 month	3.95±0.927		

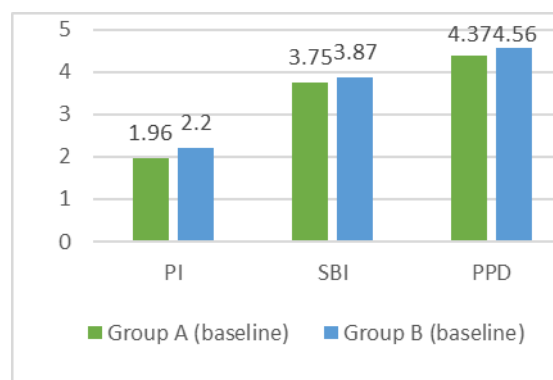
Table 1: Intergroup comparison (Paired t test) of clinical parameters at baseline and 1 month. p-value \leq 0.05 is statistically significant.

After 1 month, the results revealed a statistically significant difference between the two groups for Plaque Index (PI) and Sulcus Bleeding Index (SBI), whereas for Probing Pocket Depth (PPD), the difference was not statistically significant as depicted in graph 2.

Mean score for plaque Index (PI) in the Group A was significantly lower (0.64 ± 0.36) compared to the Group B (1.23 ± 0.63), with $t = -4.102$ and $p = 0.002$. Similarly, for Sulcus Bleeding Index (SBI), the Group A showed a significantly lower mean (0.87 ± 0.26) compared to the Group B (3.74 ± 0.73), with $t = 6.872$ and $p = 0.003$. However, for Probing Pocket Depth (PPD), the Group A showed a mean of 2.82 ± 0.84 , while the Group B showed 3.95 ± 0.92 . The difference was not statistically significant ($t = -4.134$, $p = 0.019$). Thus, after one month, the Group A demonstrated better clinical improvement in PI and SBI when compared to the Group B.



Graph 1: Baseline intergroup comparison of clinical parameters.



Graph 2: One month intergroup comparison of clinical parameters.

Intragroup comparison: A paired t-test was performed to assess the intragroup comparison within the Group A from baseline to one month for clinical parameters (PI, SBI, and PPD).

The results revealed a statistically significant reduction in all three clinical parameters after one month of



intervention in the Group A (table 2). For Plaque Index (PI), the mean value reduced from 1.54 ± 0.48 at baseline to a lower score at one month, with $t = 7.24$ and $p = 0.02$, indicating a significant improvement. Similarly, for Sulcus Bleeding Index (SBI), the baseline mean of 2.87 ± 0.73 significantly reduced after one month ($t = 25.00$, $p = 0.03$). For Probing Pocket Depth (PPD), the mean value also showed a significant reduction from 2.27 ± 0.37 at baseline to lower scores after one month, with $t = 4.93$ and $p = 0.02$. Hence, the Group A showed statistically significant improvement in all clinical parameters from baseline to one month.

Groups	Clinical indices	Time Period	Mean \pm St dev	p value
Group A	PI	Baseline	1.54 \pm	0.02
		1 month	0.48	
	SBI	Baseline	2.87 \pm	0.03
		1 month	0.73	
	PPD	Baseline	2.27 \pm	0.02
		1 month	0.37	
Group B	PI	Baseline	0.34 \pm	0.09
		1 month	0.46	
	SBI	Baseline	0.83 \pm	0.08
		1 month	0.84	
	PPD	Baseline	1.84 \pm	0.06
		1 month	0.76	

Table 2: Intragroup comparison (Independent t-test) of clinical parameters at baseline and 1 month. p-value ≤ 0.05 is statistically significant.

Although there was a reduction in the mean values of all clinical parameters from baseline to one month, the results were not statistically significant.

For Plaque Index (PI), the mean value reduced from 0.34 ± 0.46 at baseline, with $t = 4.37$ and $p = 0.09$. For Sulcus Bleeding Index (SBI), the baseline mean of 0.83 ± 0.84 showed improvement at one month, with $t = 3.46$ and $p = 0.08$.

Similarly, for Probing Pocket Depth (PPD), the mean reduced from 1.84 ± 0.76 at baseline, with $t = 410.43$ and $p = 0.06$. However, the changes observed in the Group B

for all parameters were statistically non-significant ($p > 0.05$).

Discussion:

Probiotics have been well-documented to modulate host immune responses both locally and systemically. They interact with dendritic cells, key antigen-presenting cells leading to the activation of either Th1 (T-helper cell 1) or Th2 (T-helper cell 2) immune pathways, thereby influencing the overall immune modulation. Specifically, probiotics enhance innate immunity and help regulate pathogen-induced inflammation through the activation of toll-like receptors (TLRs) expressed on dendritic cells. The Th1 response is primarily responsible for the clearance of intracellular pathogens, while the Th2 response targets extracellular pathogens. Remarkably, probiotics can elicit immune responses similar to those triggered by pathogens but without causing tissue damage or periodontal destruction.[10]

In our study, group A received *Lactobacillus paracasei* GMNL-33 at a concentration of 1 billion CFU (colony-forming units) in tablet form. This marks the first reported instance where this particular strain was developed into a tablet formulation, specifically aimed at improving its bioavailability for periodontal health. In contrast, group B was administered a powdered probiotic formulation that required dissolution in water prior to ingestion. This formulation contained a blend of strains including *Lactobacillus paracasei*, *Bifidobacterium lactis*, *Lactobacillus rhamnosus*, and *Lactobacillus brevis*, all known for their oral health promoting properties.

After one month, group A demonstrated statistically significant improvements in clinical parameters in both intragroup and intergroup comparisons. While group B also showed reductions in clinical indices, these changes did not reach statistical significance. The difference in outcomes may be attributed to the mode of delivery, strain specificity, and bioavailability of the probiotic formulations.

Several factors may account for the observed disparity in clinical outcomes between the two groups. One of the most notable differences lies in the mode of delivery and the resulting bioavailability of the probiotic strains. The tablet formulation used in group A was designed to disintegrate directly within the oral cavity, thereby



allowing the probiotic strain *Lactobacillus paracasei* GMNL-33 to come into immediate contact with the oral tissues. This mode of delivery potentially enhanced the bio-availability of probiotic, specifically the periodontal niches. In this way, the tablet likely acted in a manner similar to local drug delivery systems commonly used in periodontal therapy, providing sustained and targeted probiotic exposure to the affected tissues.

In contrast, group B was administered the probiotic in a powdered form intended for systemic intake. Once ingested, the probiotic strains had to traverse the gastrointestinal tract, undergo partial digestion, and then be absorbed before any systemic circulation could potentially deliver them to the oral cavity. This multi-step process is not only time-consuming but may also lead to degradation or loss of viability of the probiotic strains before reaching the oral tissues. Moreover, the systemic route introduces additional biological barriers such as first-pass metabolism, enzymatic breakdown, and competitive inhibition by gut microflora, all of which can compromise the efficiency and concentration of the probiotic reaching the target sites in the mouth.

Additionally, the metabolic interactions that occur during systemic absorption and transport may alter the activity or structural integrity of the probiotics, further diminishing their intended therapeutic effects. These limitations inherent to systemic delivery may explain the relatively weaker and statistically non-significant results observed in group B. In essence, while systemic probiotics can offer generalized health benefits, their ability to influence specific oral conditions may be limited unless specifically formulated for targeted oral delivery.

The specific strain used in group A *Lactobacillus paracasei* GMNL-33 has been previously reported to be effective in reducing dental caries and plaque accumulation. Its demonstrated ability to inhibit oral pathogens may have played a significant role in the favourable and statistically significant clinical outcomes observed in group A participants. In a study *L. paracasei* GMNL-33 was found to significantly reduce caries-associated salivary microbial counts in healthy adults.[11] Their findings suggest that a minimum of two weeks of oral administration may be required for this probiotic strain to exert its beneficial effects, indicating that consistent use is critical for optimal efficacy.

In addition, Lee MK et al., [12] another strain *L. paracasei* GMNL-143 has also shown potential for oral health applications. Although heat-killed, GMNL-143 retained its ability to co-aggregate with pathogenic oral bacteria and inhibit their adherence to gingival epithelial cells. Clinical studies have further demonstrated the benefits of GMNL-143 when incorporated into toothpaste, where it contributed to a reduction in gingival index scores and a decrease in *Streptococcus mutans* concentrations among patients with gingivitis. These findings underscore the promising role of specific *L. paracasei* strains, such as GMNL-33 and GMNL-143, in modulating the oral microbiome and alleviating inflammatory periodontal conditions.

Furthermore, Kim et al.,[13] reported that heat-killed *Lactobacillus paracasei* SMB092 functions as an immune stimulant by promoting the production of beta-defensins through activation of the TLR2/6 signalling pathway. In addition, *Lactobacillus paracasei* LMT18-32 has been demonstrated to produce antimicrobial substances, including bacteriocins, which inhibit the growth of *Porphyromonas gingivalis*. [14] Another strain, *L. paracasei* ET-22, exhibited significant inhibitory activity against biofilms formed by the oral pathogen *Streptococcus mutans*, not only in its viable form but also when heat-killed or through its secreted metabolites. [15] Furthermore, in patients with halitosis, a 28-day oral intake of both live and heat-killed *L. paracasei* ET-22 resulted in a noticeable reduction in volatile sulfur compound (VSC) levels and inhibitory effects on certain oral pathogens at the genus level.[16] However, despite this observation, there is currently no established or well-documented association in the literature between halitosis and these two genera, suggesting that further research is needed to clarify their potential role in oral malodour.

A meta-analysis of 12 randomized controlled trials investigating the role of probiotics in type 2 diabetes mellitus revealed that 10 of the studies reported a statistically significant reduction in HbA1c, fasting insulin levels, and HOMA-IR scores following *Lactobacillus* supplementation, indicating its potential therapeutic benefit in improving glycaemic control and insulin sensitivity in such patients.[17]

In the treatment of chronic gingivitis patients, a probiotic mouthwash was nearly as effective as CHX in reducing the plaque and bleeding scores. It showed better results in



all clinical parameters than herbal and povidone-iodine mouthwashes.[18]

The major limitations of the study are small sample size, short duration of follow-up, lack of blinding, no microbiological assessment. Further long-term studies evaluating the efficacy of formulations are required.

Conclusion:

Overall, probiotic tablets appear to be a more effective adjunct to conventional therapy in improving periodontal health in patients with stage I and II periodontitis over a short-term period. However, further long-term, multicentric trials with larger sample sizes and microbiological assessments are warranted to confirm these findings and explore the underlying mechanisms.

Ethical considerations: The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. Ethical approval (Pr.663/IEC/SIBAR/2025). was obtained from the Institutional Ethics Committee of Sibar Institute of Dental Sciences, Guntur, prior to the commencement of the study.

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Conflict of interest: The author declares that there are no conflicts of interest.

Consent for publication: Informed consent was obtained from all individual participants.

Data availability: The data will be available upon considerable request made to the corresponding author.

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