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study

# Clinical and microbiological effects of the adjunctive use of probiotics in the treatment of gingivitis: A randomised controlled clinical trial

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## RELEVANT BACKGROUND

Regular mechanical removal of the dental biofilm through effective self-performed oral-hygiene practices, together with professional intervention to eliminate already established biofilms and retentive factors, are the critical elements in gingivitis management. However, a significant proportion of individuals fail to perform an effective supragingival biofilm control, while subject-based factors may modulate the inflammatory response to plaque. In these susceptible subjects, the adjunctive use of antimicrobial agents has been recommended. Unfortunately, the long-term use of antiseptics may be associated with side-effects. One alternative approach has been the use of orally administered live microorganisms (probiotics), which have been proven to possess in vitro activity against certain periodontal pathogens.

## AIMS

The purpose of this clinical trial was to evaluate the efficacy of a probiotic combination (*Lactobacillus plantarum*, *Lactobacillus brevis* e *Pediococcus acidilactici*) when used orally to control gingivitis, and to evaluate its impact on the subgingival microbiota.

## MATERIALS AND METHODS

The study was designed as a randomised, double-blinded, placebo-controlled, parallel-group clinical trial in gingivitis patients, including subjects with minor attachment loss ( $\leq 2$  mm).

Subjects were randomly assigned by blocks to either the test group (chewing, twice per day during six weeks, tablets containing the probiotic strain) or the control group (same regimen, but using tablets containing the placebo).

The primary outcome variable was changes in mean gingival index (GI). The secondary outcomes were changes in mean plaque index (PI) and mean angulated bleeding score (AngBS). The level of compliance was assessed through a questionnaire completed by the patients.

One subgingival sample in each quadrant per patient was collected, by means of two sterile paper points. Quantitative polymerase chain reaction (qPCR) technology was used for detecting and quantifying the bacterial DNA. The qPCR amplification was performed for five putative periodontal pathogens [*Aggregatibacter actinomycetemcomitans* (AA), *Porphyromonas gingivalis*, *Tannerella forsythia* (TF), *Fusobacterium spp.*, and *Campylobacter rectus*].

The outcome variables were compared within and between groups. A multiple linear regression was run.

# results

- Out of 59 enrolled patients, 52 completed the study: 29 in the test and 23 in the control group.
- No statistically significant differences in mean GI between groups were detected at baseline and at week 6.
- In both groups, mean GI decreased significantly from baseline to week 6 [-1.06 (0.3) and -1.08 (0.3);  $p < .001$ ].
- At week 6 the number of sites GI = 3 in the test group was significantly lower than in control group (0 vs 5;  $p = .042$ ). The percentage of subjects with GI >1 was greater in control group (0% vs.12%,  $p = .080$ ).
- Most subjects harboured the pathogens at both visits in both treatment groups, without differences between study visits.
- At week 6, TF was significantly reduced only in the test groups [-1.06 (1.6);  $p = .008$ ]. AA was reduced in both groups [-0.97 (1.3) and -1.06 (1.3);  $p = .044$  and  $p = .017$ ]
- Multiple regression analysis identified the concentration of TF and AA as significant linear predictors of the number of individual GI scores = 3 and of mean GI, respectively.
- At week 6, mean AngBS was higher in treatment group ( $p = .044$ ), but there were no significant differences between groups in terms of mean AngBS changes between baseline and 6 weeks ( $p = .061$ )
- There were no significant differences in terms of compliance between groups.



## LIMITATIONS

- The use of mean GI as the main outcome measurement for assessing the efficacy of the adjunctive use of new agents for gingivitis management, such as probiotics, may not be appropriate. The most frequently reported event (GI  $\leq 1$ ) may mask the positive effect of the agent on sites with clear signs of inflammation (GI  $\geq 2$ ). The lack of statistically significant differences in mean GI changes could also be explained by the selection of mild-moderate gingivitis cases, the effects of non-surgical therapy, and the limited follow-up.



## CONCLUSIONS

- It can be concluded that the use of probiotic tablets containing a specific combination of probiotics was able to reduce the number of sites with severe inflammation in gingivitis patients, when compared with the use of similar tablets without the probiotic strains during the etiological therapy of gingivitis.
- Sites GI = 3 at the baseline were significantly reduced by the adjunctive use of probiotics, furthermore the overall GI was reduced. In addition, all subjects in the probiotic group demonstrated gingival health (as identified with a mean GI <1) at the re-evaluation visit, while three patients in the control group still showed gingival inflammation (mean GI >1).
- The adjunctive use of the probiotic also demonstrated a significant microbiological impact by reducing the counts of TF.



## IMPACT

- This study shed light on the possible effect of probiotics as adjunctives to the aetiological therapy of the disease in patients affected by a high level of gingival inflammation associated with the presence of periodontal pathogen bacteria. Probiotics could, through their specific mechanisms, allow the early colonisation of the oral ecological niches by the commensal flora to the detriment of pathogen bacteria associated with gingival inflammation.



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