

Evaluation of the intestinal colonization by microencapsulated probiotic bacteria in comparison to the same uncoated strains.

Mario Del Piano M.D.^{a*}, Marco Ballarè M.D.^a, Stefania Carmagnola M.D.^a, Michela Pagliarulo M.D.^a, Silvano Andorno M.D.^a, Paolo Strozzi B.S.^b, Luca Mogna B.S.^c, Filomena Sforza M.D.^{oo}, Lucio Capurso M.D.^{ooo}

^a Gastroenterology Unit, Maggiore della Carità Hospital, Novara, Italy

^b Probiotical SpA, Novara, Italy

^c Biolab Research Srl, Novara, Italy

^{oo} Private Hospital "I Cedri", Fara Novarese, Italy

^{ooo} Centro ricerca clinica, San Filippo Neri Hospital, Roma, Italy

Abstract

Background. Beneficial findings concerning probiotics are increasing day by day. However, one of the most important parameter which affects the probiotic activity of a microorganism is its survival during the gastro-duodenal transit. Some microencapsulation techniques could be applied to bacterial cells in order to improve this parameter.

Methods. A comparison between the intestinal colonization by microencapsulated bacteria and the same not microencapsulated strains has been conducted by a double blind, randomized, cross-over study. The study, carried out between April and July 2005, involved 44 healthy volunteers. In particular, subjects were divided into two groups: group A (21 subjects) was treated with a mix of probiotic strains *Lactobacillus plantarum* LP01 (LMG P-21021) and *Bifidobacterium breve* BR03 (DSM 16604) in an uncoated form, group B (23 subjects) was given the same strains microencapsulated with a gastroresistant material. The not microencapsulated strains were administered at 5×10^9 CFU/strain/day for 21 days, while the microencapsulated bacteria were given at 1×10^9 CFU/strain/day for 21 days. At the end of the first period of treatment with probiotics a 3-weeks wash-out phase has been included in the study protocol. At the end of the wash-out period the groups were crossed: in detail, group A had the microencapsulated and group B the uncoated bacteria. The administered amounts of each strain were the same as the first treatment. The quantitative evaluation of intestinal colonization by strains microencapsulated or not was made by faecal samples examination at the beginning of the clinical trial, after 10 days and after 21 days of each treatment period. In particular, faecal heterofermentative Lactobacilli and Bifidobacteria have been counted.

Results. A statistically significant increase in the faecal amounts of Lactobacilli and Bifidobacteria was recorded in both groups at the end of each treatment compared to d_0 or d_{42} ($p < 0.0001$ and $p < 0.0001$ at d_{21} , $p < 0.0001$ and $p < 0.0001$ at d_{63} for Lactobacilli and Bifidobacteria, respectively), confirming the ability of the two strains to colonize the human gut, either in a gastro-protected form or not. Subjects treated with the microencapsulated bacteria reported a kinetics of intestinal colonization quite similar to subjects who received not coated strains.

Conclusions. Probiotics are able to exert many different beneficial effects on the human host. These effects are mediated by the number of viable cells which reach the gut. The microencapsulation technique used in this study is a valid strategy to significantly improve gastroresistance of strains, thus enhancing their probiotic activity and allowing the use of a five-times lower amount.

Key words. Probiotic strain, microencapsulation, intestinal colonization, gastro-duodenal transit.