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Placebo-controlled assessment of the safety and efficacy of a food supplement for patients with acne

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Introduction: A food supplement (FS, AR2324) has been developed containing agents (biotin, riboflavin, pantothenic acid, burdock, *saccharomyces cerevisiae var boulardii*) that target the pathophysiology of acne, including barrier function, sebum production, inflammation and intestinal flora equilibrium.

Objective: To evaluate the effect of the FS on skin sebum levels and acne lesions.

Method: This randomized, double-blind, placebo-controlled trial enrolled adults with mild-to-moderate facial acne. Patients orally consumed one sachet of the FS or placebo daily, for 12 weeks. Efficacy was evaluated at 4, 8 and 12 weeks through instrumental measurements and clinical evaluation by a dermatologist. Patients completed a quality of life questionnaire in relation to the severity of acne.

Result: Forty patients were enrolled in the study (20 FS; 20 placebo). There was a significant reduction in sebum production with the FS compared with placebo at 4 ($p<0.01$), 8 and 12 weeks (both $p<0.001$); at 12 weeks there was a 20% reduction in sebum production with the FS versus baseline ($p<0.001$). The number of inflammatory acne lesions was significantly reduced with the FS compared with placebo at 4, 8 and 12 weeks (all $p<0.001$); a 35% reduction was observed at week 12 with the FS compared with baseline ($p<0.001$). At 12 weeks, more patients in the FS group considered their acne to be a minor problem or not a problem compared with placebo (85% versus 65%). No adverse events were reported.

Conclusion: The FS improved sebum levels and acne severity in patients with mild-to-moderate acne. Declaration of conflict of interest: RM is an employee of Meda, a Mylan company; AZ is an employee of Meda, a Mylan company; FG is a consultant scientific advisor for Meda, a Mylan company.

Biography

Raffaella Mantegazza completed her PhD in Plant Molecular Biology from the University of Milan. She has been Global Medical Affairs Lead of the Centre of Excellence Dermatology at Meda, a Mylan company, since 2016.

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