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Modulation of the gut microbiome and Firmicutes phylum reduction by a nutraceutical blend in the obesity mouse model and overweight humans: A double-blind clinical trial

Introduction

Gut dysbiosis/dysmetabolism and meta-inflammation are associated with overweight/obesity, extending beyond genetics and socioeconomic factors (Nehmi-Filho, Santamarina, et al., 2023). According to projections, the number of adults affected by obesity is expected to surpass 1.3 billion by 2030. In Brazil, the prevalence of overweight in adults was 40.5% in 2020 (Kodaira et al., 2021). Overweight and obesity are closely linked to gut dysbiosis/dysmetabolism and disrupted De-Ritis ratio [aspartate aminotransferase (AST)/alanine aminotransferase (ALT) ratio], which may contribute to chronic noncommunicable diseases onset. Concurrently, extensive research explores nutraceuticals, and health-enhancing supplements, for disease prevention or treatment.

Methods

Thus, sedentary overweight volunteers were double-blind randomized into two groups: Novel Nutraceutical_(S) (without silymarin) and Novel Nutraceutical (with silymarin). Experimental formulations were orally administered twice daily over 180 consecutive days. We evaluated fecal gut microbiota, based on partial 16S rRNA sequences, biochemistry and endocrine markers, steatosis biomarker (AST/ALT ratio), and anthropometric parameters.

Results

Post-supplementation, only the Novel Nutraceutical group reduced *Clostridium clostridioforme* (Firmicutes), Firmicutes/Bacteroidetes ratio (F/B ratio), and De-Ritis ratio, while elevating *Bacteroides caccae* and *Bacteroides uniformis* (Bacteroidetes) in Brazilian sedentary overweight volunteers after 180 days.

The analysis of fecal microbiota in both overweight volunteers and obese mice revealed significant influences of the Novel Nutraceutical on taxonomic profiles and anthropometric measures, such as WHR and weight gain, respectively. The Novel Nutraceutical_(S) (without silymarin) significantly decreased the De-Ritis ratio at T180 (1.47 ± 0.37) compared to baseline ($T0 = 2.47 \pm 1.14$) (Table 1). Although statistical significance in this ratio was not observed in the group of overweight volunteers receiving the Novel Nutraceutical after 180 days (2.00 ± 0.82) of supplementation, a reduction compared to the baseline ($T0 = 2.62 \pm 1.18$) (Table 1).

In summary, the results presented here allow us to suggest the gut microbiota as the action mechanism of the Novel Nutraceutical promoting metabolic hepatic recovery in obesity/overweight non-drug interventions.

Discussion

Our findings suggested that the Novel Nutraceutical exhibited a predictive capacity in reshaping the microbiota, leading to enhancements in clinical parameters such as WHR and the De-Ritis ratio (Nehmi-Filho, Santamarina, et al., 2023). These outcomes imply that microbiota modulation is a primary mechanism of action for the Novel Nutraceutical in improving metabolic parameters and contributing to hepatic function recovery.

Despite limitations, such as sample size and gender distribution, our study suggests that the 180-day post-supplementation administration of the Novel Nutraceutical effectively altered intestinal microbiota composition and an important liver damage biomarker in sedentary overweight Brazilian volunteers, independent of exercise or diet (Nehmi-Filho, Santamarina, et al., 2023). These findings underscore the translational impact of supplements, bridging the gap between scientific research and clinical practice, and making nutraceuticals more pragmatic and applicable for medical practitioners.

References

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