P43 – Efficacy of the treatment with *Bifidobacterium breve* B632 and *Bifidobacterium breve* BR03 on endocrine response to the oral glucose tolerance test in pediatric obesity: a cross-over double blind randomized controlled trial

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Background: Studies show that lean and overweight individuals have a different gut microbiota composition involved in pathogenic mechanisms linked to obesity. Few studies have been done in humans, in particular in pediatrics, to evaluate how the manipulation of the gut microbiota through probiotics could impact on obesity and its associated comorbidities.

Objective: To clarify if *Bifidobacterium (B.) breve* B632 and *B. breve* B03 are able to rescue metabolic homeostasis and reduce chronic inflammation in obese children.

Methodology: This is a concluded cross-over double blind RCT on 100 obese children and adolescents (6-18 years) with insulin-resistance. The subjects were on diet training and were randomly treated with a concentration of 3x10^8 CFU of *B. breve* B632 and *B. breve* B03 (Neobifi®; Probiotical S.p.A), or placebo once daily for 8 weeks over two separate treatment periods, with a wash-out period of 4 weeks (T0-T4). Clinical, biochemical (including an OGTT) and faecal samples were analysed. This study was supported by Nutricia Foundation Grants (2015, 2016).

Results: The preliminary results are related to the first step of the cross-over study (T0-T1). At T1, after the first 8 weeks of treatment, treatment (TRT) subjects had lower levels of waist to height ratio ($p<0.05$), fasting insulin ($p<0.03$), HOMA-IR ($p<0.03$), and higher insulin sensitivity as ISI ($p<0.04$) and QUICKI indexes ($p<0.02$) than the placebo (PLC) group. BMI SDS ($p=0.08$), AST ($p=0.06$) and ALT ($p=0.08$) were nearly to significance higher in the PLC than in TRT subjects. No differences in selected stool microbial populations were detected.

Moreover, waist circumference ($p<0.0001$), diastolic blood pressure ($p<0.007$), AST ($p<0.02$), HOMA-IR ($p<0.0001$), glucose levels at 120 min after OGTT ($p<0.01$) and IL6 ($p<0.02$) decreased, whereas QUICKI ($p<0.0001$) and ISI ($p<0.006$) indexes, and disposition index ($p<0.0001$) increased in the TRT group from T0 to T1. Apart from variability in SCFA among patients, 2- and 3- methyl-, methyl ester butanoic, and acetic acids were different after the treatment. NGS data on stool samples are ongoing.

Conclusions / Implications for practice: The treatment with *B. breve* B632 and *B. breve* B03 could reduce inflammation and ameliorate glucose metabolism. The confirmation of these data at the end of the analysis, could have a crucial impact on the care strategies for pediatric obesity.

References

NCT03261466