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BUTYRATE AGAINST PAEDIATRIC OBESITY: RESULTS OF THE BAPO TRIAL

S. Coppola[1,2], R. Nocerino[1,2], L. Paparo[1,2], C. Di Scala[1,2], L. Voto[1,2], A. Luzzetti[1,2], V. Giglio[1,2], R. Berni Canani[1,2,3,4]

[1]*Dipartimento di Scienze Mediche Traslazionali, Università degli Studi di Napoli Federico II*

[2]*ImmunoNutrition Lab, CEINGE Biotecnologie Avanzate, Università degli Studi di Napoli Federico II*

[3]*Laboratorio Europeo per lo studio delle malattie indotte da alimenti (ELFID), Università degli Studi di Napoli Federico II*

[4]*Task Force di Ateneo per gli Studi sul Microbioma, Università degli Studi di Napoli Federico II*

Objectives and Study

Paediatric obesity is global public health challenges. Preclinical studies have shown that the short chain fatty acid butyrate could exert beneficial effects against obesity. We aimed to see whether oral butyrate could exert beneficial effects in obese children/adolescents.

Methods

The BAPO trial (butyrate against paediatric obesity) was a randomized, quadruple-blind, placebo controlled, clinical trial on obese paediatric patients (Body Mass Index (BMI) >95th percentile for age and sex) of both sexes, aged 7-16 years, observed at a tertiary center for paediatric nutrition. After collection of informed consent by the patients and their tutors/parents, subjects were randomly assigned according to the randomization list to one of the two 6-month intervention groups: active group, standard care for paediatric obesity + sodium butyrate (20 mg/kg body weight/day); or placebo group, standard care for paediatric obesity + placebo. Study products were provided in capsules packed in identical boxes with the same aspect, color and weight. The primary outcome was a BMI z-score reduction of $\geq$ 0.25 after 6-month intervention. Secondary outcomes were the evaluation of BMI, waist circumference, HOMA-index and eating behaviors (using a 3-day food record). At baseline and at the end of treatment, a blood sample was collected from all study subjects to evaluate fasting glucose, fasting insulin, plasma triglycerides, total/LDL/and HDL cholesterol, fasting serum ghrelin and miRNA-221 expression (a miRNA obesity related, whose expression was assessed in peripheral mononuclear blood cells PBMCs).

Results

54 obese patients were enrolled and randomly assigned to two intervention groups (27 per group); 6 subjects were lost to follow up and 48 subjects completed the study: 23 in active group and 25 in placebo group. At baseline, main demographic and clinical features of the 2 study groups were similar. The rate of subjects with BMI z-score reduction of $\geq$ 0.25 was significantly lower in active groups compared to placebo group. At the end of intervention, a significant reduction of daily calories intake and a macronutrient redistribution toward the recommended range were observed in both groups. Waist circumference and BMI was significant lower in active group at the end of intervention. A significant reduction of fasting insulin, HOMA-index and LDL was observed in active group. Finally, a significant down-regulation of peripheral miR-221 expression and a significant decrease of fasting serum ghrelin was observed in patients treated with sodium butyrate.

Conclusions

This is the first evidence of the therapeutic role of butyrate in paediatric obesity. Our preliminary results suggest that the beneficial effects are mediated in part by epigenetic mechanism, involving miRNA 221 expression, and by hormonal regulation of food intake played by ghrelin, a relevant regulator of appetite, body weight and energy homeostasis.

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