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A protein-enriched low glycemic index diet with omega-3 polyunsaturated fatty acid supplementation exerts beneficial effects on metabolic control in type 2 diabetes

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ABSTRACT

Aims: The current study aims to investigate practicability and effects of a combined dietary intervention with increased relative protein content supplemented with omega-3 polyunsaturated fatty acids (PUFA) on metabolic control and inflammatory parameters in a real life situation in type 2 diabetes patients.

Methods: In this observational study we advised thirty mostly obese patients with type 2 diabetes to follow a protein-enriched diet with carbohydrates of low glycemic index (low GI) and moderate fat reduction supplemented with omega-3 PUFA for 24 weeks. Primary efficacy parameter was the change in HbA1c; secondary parameters included changes in systemic inflammation (measured by ultrasensitive C-reactive protein, usCRP), body weight, waist circumference, fat mass. The study is registered at clinicaltrials.gov (NCT01474603).

Results: The dietary intervention significantly reduced the primary efficacy variable HbA1c from a baseline value of 63 ± 11 mmol/mol to 59 ± 14 mmol/mol ($P = 0.033$) and 56 ± 12 mmol/mol ($P = 0.001$) after 12 and 24 weeks, respectively. In addition, usCRP decreased significantly at 24 weeks ($P = 0.039$). Waist circumference, an important indicator for cardiometabolic-risk and silent inflammation, decreased from baseline 116.0 ± 14.1 cm to 114.9 ± 13.5 cm ($P = 0.019$), 114.0 ± 14.4 cm ($P = 0.001$), and 112.7 ± 13.4 cm ($P = 0.049$), after 3, 12 and 24 weeks, respectively.

Conclusion: Counseling a protein enriched and low glycemic index diet supplemented with long-chain omega-3 PUFA in a real-life clinical setting improves glycemic control and also reduces waist circumference and silent inflammation in overweight or obese patients with type 2 diabetes.

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1. Introduction

Type 2 diabetes has developed to a major health issue as a consequence of the obesity epidemic [1]. In addition to metabolic derangements and the treatment, patients with type 2 diabetes face an enormous risk for cardiovascular disease partly mediated by elevated blood pressure and dyslipidemia. Recent research emphasizes the importance of inflammatory reactions for the development of both diabetes and cardiovascular disease [2–6]. The chronic inflammatory changes induced by obesity are subclinical in a sense that they do not provoke classical inflammatory symptoms such as pain, but are nevertheless sufficient to promote clinical disease on a long term. Moreover, silent inflammation lingers for years and causes organ damage that subsequently leads to chronic diseases such as type 2 diabetes and myocardial infarction. Hence measures to prevent cardiovascular disease in diabetes patients should not be limited to metabolic control but target inflammatory changes as well.

Lifestyle changes are first line interventions to improve glycemic control in diabetes patients. However, there is considerable discussion with respect to the optimal dietary composition in type 2 diabetes. Whereas most of the national guidelines recommend rather high dietary carbohydrate contents (approximately 55 en%), others have challenged this opinion. Notably, some of the prominent diabetes institutions such as the Joslin Diabetes Center, Boston, MA, propose somewhat higher amounts of protein at the expense of carbohydrates for the management of overweight and obese patients with type 2 diabetes [7]. Studies have shown that even slightly elevated dietary protein content particularly in combination with carbohydrates of low glycemic index improve weight loss and weight maintenance [8]. On the other hand, limiting fat content in patients with usual fat consumption (approximately 37 en%) could help to reduce weight further [9]. However, meta-analysis revealed that patient rather prefer diets with reduced carbohydrate/elevated protein content compared to low-fat diets, rendering the latter less effective on long term [10].

In addition to improving glycemic control and weight, dietary interventions should also reduce chronic inflammatory alterations in order to prevent cardiovascular disease. Long chain omega-3 polyunsaturated fatty acids (PUFA) derived from fish oils, namely eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), exert potent anti-inflammatory effects by altering fatty acid-derived lipid mediator production [11,12]. On the other hand, by decreased consumption of omega-3 PUFA over the past century [13] and increased intake of refined carbohydrates, modern western diet might promote subclinical ("silent") inflammatory changes [14]. We have recently shown in experimental and clinical studies that high-dose omega-3 PUFA promote anti-inflammatory lipid mediator production and improve adipose tissue inflammation in morbidly obese patients [15,16].

In the current study, we aimed at investigating practicability and effects of a combined anti-inflammatory dietary intervention on metabolic control and inflammatory parameters in a real life situation in an observational pilot study. Patients with type 2 diabetes were advised to keep a protein-enriched diet with carbohydrates of low glycemic index and moderate fat reduction supplemented with n-3 PUFA. We hypothesize that in a setting comparable to standard nutritional support in clinical practice, HbA1c and C-reactive protein concentrations were reduced along with a reduction in body weight, despite limited adherence to the diet.

2. Methods

2.1. Study population

Eligible type 2 diabetes patients were between 18 and 75 y of age and overweight or obese (Body Mass Index – BMI, >25 kg/m^2) who regularly visited the diabetes outpatient clinics of either the General Hospital and Medical University of Vienna or the Health Center South, Vienna. All had received dietary counseling on a recommended diet in the past including 50–55 en% carbohydrates, 10–20 en% protein and <35 en% fat and were treated with oral antidiabetic drugs and/or insulin. A change in the anti-diabetic treatment was discouraged during the treatment period and did not occur. Patients were excluded in case of a change in the antidiabetic medication within the past two months; acute illness within the past two weeks; human immunodeficiency virus infection; hepatitis or other significant liver disease (except hepatic steatosis); severe or untreated cardiovascular, renal, or pulmonary disease; macroproteinuria; untreated or inadequately treated clinically significant thyroid disease; anemia; active malignant disease; inborn or acquired bleeding disorder; pregnancy or breastfeeding. All patients have given written informed consent before taking part in the study.

2.2. Study design and intervention

This clinical trial was a non-controlled, observational pilot study, performed in compliance with the Helsinki Declaration of 1975 as revised in 1983 and with Good Clinical Practice guidelines. The trial was approved by the Ethics Committee of the Medical University of Vienna (EK-no. 784/2011) and was conducted at the Clinical Division of Endocrinology and Metabolism, Department of Medicine III, Medical University of Vienna. The study is registered at clinicaltrials.gov (NCT01474603).

All recruited patients received personal nutritional counseling for about 1 to 1½ h on the dietary regimen and were asked to keep a low glycemic index diet with a nutrient ratio of 40 en% carbohydrates, 30 en% protein and 30 en% fat. In addition, patients were treated with 4 capsules of long-chain n-3 PUFA (EnerZONA Omega 3 RX; Enervit S.p.a., Milan, Italy) daily containing 1.6 g EPA and 0.8 g DHA. A starter package was provided with information on the diet, some product samples such as shakes and bars in the appropriate nutrient composition and 180 capsules of Omega 3 RX. Each subject was advised to maintain usual physical activity.

The intervention lasted for 6 month and participants returned for follow-up visits at approximately 3, 12 and 24 weeks after enrollment. At 3 weeks, participant questions concerning the diet were discussed, anthropometric measurements taken (BMI, hip and waist circumference, systolic and