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Impact of protein supplementation after bariatric surgery: A randomized controlled double-blind pilot study

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ABSTRACT

Objectives: Bariatric patients are at risk of protein deficiency. The aim of this study was to determine possible benefits of postoperative protein supplementation weight reduction, body composition, and protein status.
Methods: Twenty obese patients who underwent bariatric surgery were randomized either to the protein (PRO) group, which received a daily protein supplement over 6 months postoperatively, or to the control (CON) group, which received an isocaloric placebo in a double-blind fashion. Data on protein and energy intake, body weight, body composition, blood proteins, and grip force was collected preinterventionally and at 1, 3, and 6 months postoperatively.
Results: In both groups body weight was significantly reduced to a similar extent (after 6 months: PRO group 25.4 ± 7.2%, CON group 20.9 ± 3.9%; intergroup comparison $P > 0.05$). Protein intake was steadily increased in the PRO group, but not in the CON group, and reached maximum at month 6 (25.4 ± 3.7% of energy intake versus 15.8 ± 4.4%; $P < 0.001$). In the PRO group, body fat mass loss was higher than that in the CON group (79% of absolute weight loss versus 73%; $P = 0.02$) while lean body mass loss was less pronounced (21% versus 27%, $P = 0.05$). Blood proteins and grip force did not differ at any time point between the two groups.
Conclusions: The present study suggests that protein supplementation after bariatric surgery improves body composition by enhancing loss of body fat mass and reducing loss of lean body mass within the 6 months follow up.

Introduction

Despite the advantages of bariatric surgery, attention needs to be paid to the possible risks, including postoperative nutritional deficiencies [1,2]. It has been shown that bariatric surgery leads to an increased risk for developing protein malnutrition [3,4]. Possible reasons might be the restricted food intake and the malabsorption of nutrients after surgery [5–7]. Postoperative occurrence of vomiting or different food intolerances may further enhance the risk [8,9]. As a consequence, reduction in blood protein levels, and finally in muscle mass has to be expected [10]. Indeed, numerous studies indicate a decrease in levels of albumin and prealbumin, and a significant reduction in lean body mass resulting from protein deficiency after bariatric surgery [4,5,9,11,12].

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Dietary proteins have shown to play an important role in body weight regulation. A protein-rich diet attains satiety and thereby facilitates reduction in overall energy intake [13]. It enhances food-induced thermogenesis [14], and, ideally in combination with exercise, preserves lean body mass, and thus resting energy expenditure, which in turn leads to an improvement of long-term energy balance [7,14–16]. Therefore, protein supplements might facilitate weight loss, especially body fat loss, and protect against muscle mass wasting in patients who underwent bariatric surgery. The aim of the present randomized, placebo-controlled, double-blind pilot study was to test the efficacy of protein supplementation following bariatric surgery regarding body weight reduction, body composition, as well as protein status and muscle function.

Materials and methods

Patients

The study was conducted at the Department of General Surgery of the University Hospital Tübingen, Germany. Thirty-five obese patients with an indication for laparoscopic sleeve gastrectomy (LSG) or laparoscopic Roux-en-Y gastric bypass (LRYGB) were consecutively enrolled. The indication for surgery was carried out in routine clinical setting, independent of the trial, according to the German S3 guideline [17]. Recruiting was conducted between November 2011 and July 2012. Informed consent, which was approved by the ethical committee of the Medical Faculty of the University Hospital of Tübingen, was obtained from all individual participants included in the study. According to the inclusion criteria, the study participants were between 18 and 65 y and had a body mass index $\geq$35 kg/m^2. Patients were excluded before trial commencement if they had any renal diseases. Additionally, subjects were excluded post entry if they did not take at least 80% of the individually calculated intervention product amount per day, or if they did not consume the intervention product for more than 2 d per week.

Study design and randomization

The study was performed in a randomized, controlled, double-blind fashion. Study visits were performed between November 2011 and December 2012. Patients fulfilling all study criteria, were block-randomized (block size of four leading to six block permutations) to one of two treatment groups. Microsoft Office Excel 2007 (Microsoft Corporation, Redmond, WA, USA) was used to generate random numbers defining the block order. Two randomization lists were used, one for each type of surgery. Patients allocated to the intervention group, hereinafter referred to as the PRO group, received protein supplements daily over 6 months (mo) after surgery. Patients allocated to the control group, hereinafter referred to as the CON group, received a placebo product. The study participants and the care givers were blinded.

Treatments

All patients received nutritional counseling by a dietitian within the routine clinical setting before discharge from the hospital, aiming to assure nutrient deficiencies.

Both study groups received isocaloric powdered study products with a similar look, smell, and analog chemical characteristics, including high solubility. Both products were filled in identical packages to enable the blinding. For the PRO group, the protein powder Resource Protein 88 from Nestlé HealthCare Nutrition GmbH, Munich, Germany, containing 88 g milk protein/100 g powder, was used. For the CON group, a pure maltodextrin powder was chosen (Resource Maltodextrin, Nestle HealthCare Nutrition GmbH), which was supplemented with different micronutrients to obtain an analog situation to the protein powder regarding amounts of micronutrients. The two products had an almost equal energy content of 369 kcal/100 g (protein product) and 381 kcal/100 g (placebo product), respectively. Patients of both groups were advised to take a dose of 15 g per day during the first postoperative month. In month two to six postoperatively, the doses were increased to 30 or 35 g per day depending on body height. If the height of the patient was <163 cm, 30 g per day were administered, otherwise 35 g per day. This dosage was chosen on the basis of other trials in which supplemental protein was administered in addition to the protein intake from food [18]. All patients were asked to document any discrepancy from the required doses.

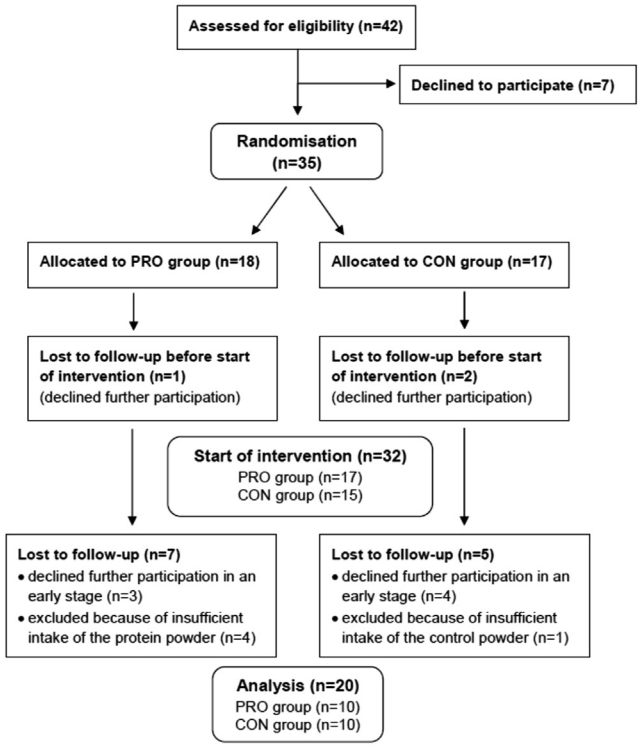

Fig. 1. Flow chart of patients in the trial. CON, control group; PRO, group protein group.

Study visits

Examinations were conducted 1 day before bariatric surgery and 1, 3, and 6 mo postoperatively. At each study visit, anthropometric parameters were measured and blood samples were taken. Patients were interviewed about the powder intake and sporting activities since the last consultation. At each visit, physical activity and health related quality of life were assessed by using the standardized questionnaires 'International Physical Activity Questionnaire' and 'Impact of Weight on Quality of Life.' Based on four day dietary food records, protein intake from food and supplements as well as total energy intake were quantified at each postoperative study visit. All data was recorded in an approved case report form.

Clinical and biological assessment

Body weight was measured after an overnight fast, using a calibrated scale and height was measured using a calibrated measuring rod. Body mass index was calculated. Body composition was assessed by bioelectrical impedance analysis using the Nutriguard-M system (Data Input GmbH, Darmstadt, Germany) according to the manufacturer's instructions. Data was analyzed using the software Nutri-Plus, version 5 (Data Input, Darmstadt, Germany).

Table 1
Baseline characteristics

Characteristic	PRO	CON
Number	10	10
Sex		
Females (n, %)	9, 90	8, 80
Males (n, %)	1, 10	2, 20
Bariatric procedure		
LSG (n, %)	8, 80	7, 70
LRYGB (n, %)	2, 20	3, 30
Age (years)	43.4 ± 13.3	47.0 ± 11.9
Body weight (kg)	143.4 ± 29.1	137.1 ± 15.5
BMI (kg/m^2)	52.0 ± 7.6	49.0 ± 5.1