Comparison of two low-calorie diets: A prospective study of effectiveness and safety


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ABSTRACT. Objective: To evaluate the cost-effectiveness and safety of two distinct low calorie diets (LCD). Design: Prospective controlled study. Methods: 67 obese patients [body mass index (BMI) 40 kg/m²] were included in two study groups. Group A: 26 patients followed a 458 kcal diet given in three meals for 1 month. Group B: 41 patients followed a 800 kcal diet for 3 months and with outpatient control. Measurements: Anthropometric, cardiovascular risk and nutritional profile changes were evaluated, as well as total direct and indirect costs, and the incidence of complications. Results: No significant initial differences were observed between the two study groups. Eighty-six point two per cent of the patients completed the therapy correctly. After treatment a significant decrease was observed in the following variables for both groups, but no differences were detected between Groups A and B: mean weight loss (A= 9.28 kg, B= 8.7 kg), ponderal loss percentage (A/B= 7.2/6.8%), glycemia (A/B= 18.6/12.1 mg/dl), systolic blood pressure (SBP) (A/B= 11.8/6.5 mmHg), diastolic blood pressure (DBP) (A/B 5.9/6.8 mmHg), and final insulin-resistance (IR) index (A= 4.4, B= 4.3). Group A had the highest drop in total cholesterol (37.7 vs 8.1 mg/dl) and triglycerides (54.4 vs 2.5 mg/dl). No changes were observed in ureic acid, renal function and serum albumin. Thirty-six patients (55.3%) suffered trivial complications associated to the VLCD (16.9% gastrointestinal, 20% anxiety), with no differences between groups. Group A patients were on sick leave due to asthenia, and two patients in this group had serious complications (transient ischemic attack and atrial fibrillation). The total cost of Group A treatment was 3018.9 against 582.6 euros for Group B. Conclusions: The 3-month 800 kcal/day VLCD was more cost-effective and safer than the 1-month 458 kcal/day diet.

INTRODUCTION

Obesity is a multifactorial chronic disease. Over the last years, it has reached epidemic proportions with important social, health and economic consequences. The prevalence of excess weight is increasingly alarming in Europe, and although it is lower than that estimated for the USA, it is following the same rising tendency.

In 1997, the prevalence of obesity among adults in Spain was 13.4%, while prevalence of overweight and obesity was of approximately 50%. These values surely underestimate the current situation in our country (1). It is well established that increased patient morbidity and mortality is obesity-related, reducing life expectancy and quality of life, and can be associated to a growing use of limited health care resources (2-5). Body mass index (BMI) has been correlated to annual inpatient days, cost of pharmacy services, and the number and cost of outpatient visits (6). The presence of conditions such as coronary heart disease, hypertension, and especially diabetes, largely explain the increased use of these resources. The reality of the problem lies in the limited health care resources and the magnitude of obesity. It is necessary to develop clinical guidelines for the treatment of obesity based on cost-effectiveness studies that will allow the optimization of the available resources. Therefore, a prospective study has been designed to evaluate the effectiveness of two low calorie diets (LCD) in patients with morbid or extreme obesity (BMI ≥40 and ≥50 kg/m²). The effectiveness of these diets was assessed as ponderal loss and cardiovascular risk indicators (CVR), economic cost and safety.

Key-words: Obesity, body mass index, low-calorie diet, cost-effective, metabolic syndrome.
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MATERIALS AND METHODS

Subject selection

Individuals aged 18 yr or older, classified as obese class III and IV (defined as BMI ≥40 kg/m² and ≥50 kg/m², respectively), or severe obesity were included in the study. All individuals presented in their clinical follow-up a confirmed failure of conventional treatment with a balanced hypocaloric diet and pharmacological drugs, and correct therapeutic compliance. Additionally, they were either preparing for bariatric surgery, or other surgery types that required general anesthesia, or were preparing for a surgery that requires weight loss due to mechanical problems or respiratory failure because of obesity hyperventilation syndrome, situations in which the use of LCD are approved in our centre. Sixty-seven obese patients (21 males and 46 females; age 45.9 ± 12.3 yr; BMI 49.1 ± 7.5 kg/m²) were included in the study. Patients were supervised by the rapid ponderal loss Nutrition Unit, and followed one of two different LCD. There was an inclusion period of 16 months. All patients for whom very LCD (VLCD) were contraindicated were excluded from the study, including unstable cardiac disease (ischemic cardiopathy, arrhythmias, heart failure), recent or unstable cerebrovascular disease, kidney (creatinine ≥ 1.4 mg/dl) or hepatic failure (values of liver biochemistry twice the upper limit of normal), severe psychiatric disorders, pregnancy, age > 65 yr or social problems that could interfere with an appropriate therapeutic follow-up. Study participants did not receive any weight-loss medication, or drugs that could affect carbohydrate metabolism. During the study period, hypotension treatment was not modified.

Protocol for ponderal loss

The structured rapid ponderal loss program was carried out in a third level medical center, supervised by a team of physicians and nurses specialized in endocrinology and nutrition (Fig. 1).

Obese patients (BMI ≥40 kg/m²)

no.=67

Group A (no.=26)
(1 w inpatient, 3 w outpatient)
MTH, ECG, anthropometry, laboratory tests

Group B (no.=39)
(12 w outpatient treatment)
MTH, ECG, anthropometry, laboratory tests

4 w
Medical/nurse visit’ once a week
ECG, laboratory tests

12 w
4 w, 8 w nurse visit”

4” week, Medical/nurse last visit
Adverse events
ECG, anthropometry, laboratory tests

12” week, Medical/nurse last visit
Adverse events
ECG, anthropometry, laboratory tests

Fig. 1 - Study scheme. ’Nurse visit: weight, blood pressure, tolerance, adverse events. MTH: medical history; ECG: electrocardiogram; w: weeks.

At the beginning of the study, a personal health record was prepared for each patient, as well as a survey of dietary and physical activity habits, a questionnaire relating social and psychological attributes, Epworth sleepiness scale (7), an analogical scale for quality of life, and a physical examination, including anthropometry, blood pressure measurement (large cuff) and ECG. Patients included in the study during the first eight months of the inclusion period were assigned to Group A. Patients in this group followed a 1-month diet program, with an initial 7-day inpatient period to verify patients’ tolerance to a VLCD. The VLCD was made up of a commercial preparation (Modifast®, Novartis Nutrition) that totaled 458 kcal/day (39.3% carbohydrates, 45.4% proteins, 13.7% lipids), to be taken in three meals. Patients were monitored through outpatient follow-up once a week.

Patients included in the following 8 months of the study were assigned to Group B and followed an 800 kcal/day mixed LCD (53% carbohydrates, 24% proteins, 23% lipids). A commercial preparation (Optifast®, Novartis Nutrition) was combined with natural food for a 3-month period. Outpatient follow-up was carried out once a month. Non-calorie fluid intake was indicated (a daily minimum of 2 l) for both groups, and a 1-h walk per day.

Anthropometric and laboratory measurements

Serial anthropometric measurements and hematologic, biochemical, and hormonal evaluations were carried out in all patients after a 12-h overnight fasting period. Basal biochemical parameters were measured on a weekly basis for Group A, and for both groups at the end of the study. Insulin resistance (IR) measurements were obtained using the homeostasis model assessment for insulin resistance (HOMA-IR= fasting glucose mmol/l x fasting insulin mU/ml/22.5), validated in our Mediterranean region. IR was diagnosed when the HOMA index was ≥ 3.8, and/or fasting insulin value was ≥ 16.7 mU/ml (8).

All biochemical measurements and the lipid profile, including total cholesterol, calculated HDL (HDL-c), calculated LDL (LDL-c) and triglycerides (TG) were determined with enzymatic methods using a Hitachi Modular autoanalyzer (Roche Diagnostics, Indianapolis, IN). Plasma C-reactive protein (CRP) levels were obtained with the IMMAGE analyzer (Beckman Coulter). For insulin level determination the IMMULITE 2000 (DPC) multianalysys system was used.

Statistical analyses

All data collected were analyzed with the SPSS software and presented as intention-to-treat, using descriptive statistics and parametric tests. Unless specified, data are presented as the mean±SD. With the exception of “diastolic blood pressure (DBP), systolic blood pressure (SBP) and glycermia variations” (Kolmogorov-Smirnov Z), all other variables follow a normal distribution. The comparison between groups of quantitative variables was made using the Student’s t-test for independent data. The same test was used for paired data to evaluate changes in the various variables after the fasting period. For the analysis of categorical variables, the Chi-square test was used. Lineal association between variables was carried out using the Pearson correlation coefficient. To identify those variables associated with the worse response to the ponderal loss program, a binomial logistic regression model was used. For non-parametric variables, the Spearman correlation and the Mann-Whitney U test were applied (differences between groups). A p-value < 0.05 was considered as statistically significant.