

Impact of the hypocaloric diet using food substitutes on the body weight and biochemical profile

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SUMMARY. Recent studies using balanced hypocaloric diets with food substitutes in some meals, have presented positive results. There are no studies with the Brazilian population on the efficacy of using food substitute, together with a hypocaloric diet. Main objective of this study was to verify the effects of a hypocaloric diet using food substitutes as meal replacement on the body weight, lipid profile, and glucose and insulin plasma levels. Seventy eight subjects of both genders were selected, 20-50 years old, and a body weight index between 25 kg/m² and 35 kg/m². The study lasted for six months and it was divided in 2 phases of three months each- mass reduction for 3 months and 3 months for maintenance. The sample was randomly divided in two groups: Group A (control- 3 months of general nutritional and physical orientation followed by 3 months with 1 meal replacement) and Group B (intervention- 2 meals replacement a day plus nutritional and physical orientation for 3 months followed by 3 months with 1 meal replacement). Anthropometric measurements, percent body fat (%BF), biochemical profile and intake survey were performed at moments 0, 3 and 6 months. Both groups showed a significant decrease in %BF, weight, and consequently in their BMI, in the third and sixth month of follow up. However, weight loss in group B was higher than in group A. At the end of the treatment, 0 and 25.0% of the patients of the group A and B, respectively, presented a weight loss higher than 10% of the initial weight. Comparing the triglycerides, LDL-cholesterol and glucose levels, between the beginning and after the three and six months of treatment, there was a significant reduction in the individuals only in group B. In conclusion, the use of food substitutes as meal replacement, together with a balanced, hypocaloric diet, proved to be efficient in weight loss for Brazilian overweighted individuals.

Key words: Obesity, food substitutes, meal replacement, nutritional orientation.

INTRODUCTION

In the last decades, there was a quick increase in obesity prevalence both in developed and in developing countries (1). In Brazil, there has been a nutritional transition process, and between the years of 1974/75 and 1989, there was a decrease in the prevalence of children malnutrition (from 19.8% to 7.6%) and an increase in obesity prevalence in adults (from 5.7% to 9.6%) (2).

RESUMO. Impacto de dieta hipocalórica utilizando substitutos alimentares sobre o peso corporal e perfil bioquímico. Estudos recentes usando dietas balanceadas e hipocalóricas utilizando substitutos alimentares em algumas refeições têm mostrado resultados positivos. Não existem estudos com a população brasileira sobre a eficiência de substitutos alimentares aliados a dietas hipocalóricas. O objetivo deste estudo foi o de verificar os efeitos desta intervenção com dieta utilizando substitutos alimentares em refeições, sobre o peso corporal, perfil lipídico, e níveis de glicose e insulina. Foram selecionados 78 adultos de 20 a 50 anos, ambos sexos com Índice de Massa Corporal (IMC) entre 25 e 35 kg/m². O estudo teve a duração de seis meses sendo três de intervenção e três de manutenção. A população foi dividida randomicamente em dois grupos: A (controle, que recebeu 3 meses de orientação nutricional e de atividade física e 3 meses de substituto alimentar em uma refeição) e B (intervenção, que recebeu durante 3 meses substituto alimentar em 2 refeições e 3 meses com apenas uma refeição substituída). Análises de consumo alimentar, bioquímica, antropométrica e percentagem de gordura corporal foram realizadas ao início, três e seis meses. Ambos grupos mostraram diminuição significativa do peso corporal, % gordura corporal e IMC aos 3 e 6 meses de intervenção. No entanto o grupo B perdeu significativamente mais peso. Ao final do tratamento, nenhum caso do grupo A e 25% do grupo B, apresentaram perda de peso superior a 10% dos valores iniciais. Em relação aos valores bioquímicos, triacilgliceróis, LDL colesterol e glicose foram significativamente inferiores aos valores iniciais somente para o grupo intervenção. Concluímos que o uso de substitutos alimentares dentro de um plano de redução calórica equilibrada pode ser uma ferramenta eficiente para a perda de peso corporal em adultos brasileiros com excesso de peso.

Palavras chave: Obesidade, sobrepeso, substitutos alimentares, orientação nutricional

Since obesity presents a major association with metabolic changes, such as dislipidemia, hypertension, hyperinsulinemia and glucose intolerance(3-5), it is necessary to implement intervention and prevention measures to fight against that nutritional disorder.

A decrease of 5 to 10% of the initial weight has been shown to be effective in reducing the risk factors for cardiovascular diseases (6).

Changing life style by means of a hypocaloric and balanced

diet, together with physical activity, seems to be the most benefic strategy (7). However, one of the major difficulties in weight loss programs is treatment compliance and long-term weight maintenance.

Recent studies using balanced hypocaloric diets with food substitutes in some meals, have presented positive results concerning those two aspects (8,9). It is believed that those products have, in their formulation, an adequate nutritional composition and that they facilitate the control of calorie intake. There are no studies with the Brazilian population on the efficacy of using food substitute, together with a hypocaloric diet, and its impact on the body weight and metabolic profile of obese individuals.

ABESO, the regional branch of the IOTF (International Obesity Task Force) has presented data showing that in Brazil, 40% of adult population is overweight (19).

Nonetheless, obesity in Brazil is associated with high intake of food and sedentarism, and morbid obesity is not as prevalent as it is in the United States. Regional habits of food intake are, sometimes, maintained, using the traditional combination of rice and beans, meat and salads instead of fast food.

Therefore, the objective of the present study was to verify the effects of a hypocaloric diet using food substitutes on the body weight, lipid profile, and glucose and insulin plasma levels.

MATERIALS AND METHODS

Sample

The researchers selected 78 subjects of both genders (73 women and 5 men), with ages between 20 to 50, and a body mass index ($BMI = \text{Weight (kg)} / \text{Height (m}^2\text{)}$) between 25 kg/m² and 35 kg/m². The subjects were recruited through ads in the magazines and newspapers of the municipality of São Paulo. The study excluded individuals with previous history or presence of chronic diseases, endocrinal, psychiatric disorders, excessive use of alcohol, or under drug or dietetic treatment for weight loss in the last six months, individuals with changes in the lipid profile or lactose intolerant.

The study lasted for six months, and it was divided in 2 phases of three months each. During the first phase, the sample was randomly divided in two groups with similar ages and genders:

Group A: control group, patients were submitted to a hypocaloric diet with nutritional orientation.

Group B: study group, patients were submitted to a hypocaloric diet, with the same calorie amount of the other group, and replacing two meals, a major one (either lunch or dinner) and a small one (breakfast) with a food substitute.

In the second phase, groups A and B were submitted to a

hypocaloric diet, replacing only one meal (either lunch or dinner) with a food substitute.

Patients were assessed as to their lipid profile (total and fraction cholesterol, triglycerides) and as to their glucose and insulin plasma levels, at the beginning, and after three and six months after the beginning of the study.

The study was conducted according to the research regulating guidelines that involve human beings, which are in the CNS Resolutions, on 196/96, approved by the Ethics Committee of the Post Graduation and Research Council of the Federal University of São Paulo, protocol # 1253/02. All participants of the study were volunteers and had their consent inform taken and signed. No financial compensation was established.

Anthropometric evaluation

In order to assess, the body weight a Filizola platform scale was used, with a maximum load of 150 kg and 100 g accuracy. The scale was calibrated before each measurement, and the patients were weighed standing up, with their back to the measurement line of the scale, barefoot, and wearing a minimum amount of clothes, with their arms down and their eyes looking at a fixed point ahead of them to prevent oscillations in the measurement readings (11).

In order to measure their height, a stadiometer was used with an accuracy scale of 0.1 cm. The patient was positioned on the basis of the stadiometer, in an upright position, barefoot, with the upper limbs down at their sides, feet together, trying to make the posterior surface of the heels, pelvic waist, scapular waist, and occipital region touch the measuring scale. A cursor helped to determine the measure that corresponded to the distance between the plantar region and the vortex, being the assessed subject in aspiratory apnea and with the head oriented to the Frankfurt plan parallel to the ground (11).

In order to evaluate the body fat distribution, abdominal circumference was used, measured from the middle point between the last costal arch and the iliac crest, and the hip circumference, measured in the most protuberant side of the glutei (11). Body fat was estimated based on equations to predict body density. From this results % body fat can be calculated. Women body density, was estimated with Jackson et al. (1980) equation (12).

Dietary prescription

Patients were submitted to a dietary program with a meal plan, between 1300 kcal for those with BMI lower than 30 kg/m² and 1500 kcal for those with BMI higher than 30 kg/m². The diet was balanced with 50-55% of carbohydrate, up to 30% of total fat and 20-25% of protein regarding the total energetic value of the diet.

Individualized meal plans were developed with the help of a list of food substitutes, divided in groups and portions

with same calorie amount. Patients were told to have at least 4 to 5 daily meals, to eat larger amounts of food rich in vitamins, minerals, and fibers, such as fruit, vegetables, grains, lean meats and low-fat dairy products and to reduce the intake of saturated fat, fried food, sweets, candies and soft drinks. All the patients had a follow up every fifteen days in an individual appointment with a nutritionist.

The food substitute that was used was a "shake" offered in a liquid form (325 ml per meal) or in powder (33g of powder in 235ml of skim milk), enriched with vitamins and minerals. Nutritional composition of macronutrients is shown in Tables 1 and 2.

TABLE 1
Nutritional composition of the product 33g of powder product added to skim milk

Energy value (kcal)	220
Total fat (g)	2.5
Carbohydrate (g)	40
Protein (g)	10

TABLE 2
Nutritional composition ready-to-feed version product

Energy value (kcal)	200
Total fat (g)	1.5
Carbohydrate (g)	36
Protein (g)	11

Biochemical tests

Total and fraction cholesterol, triglycerides, glucose and insulin were tested at the beginning of the intervention and then after three and six months later.

All the tests were done when patients were fasting for 12 hours. Glucose, total and fraction cholesterol, and triglycerides were analyzed by the colorimetric enzymatic test, whereas insulin was analyzed by electrochemical luminescence.

Statistical analysis

The changes in the value of the anthropometric and biochemical variables, according to treatment group, were assessed by Generalized Estimating Equation (GEE) method (13). T-Student tests were conducted to compare changes of those measurements at each specific time point with the initial value. The test was deemed significant when p value was lower than 0.05. The statistical pack Stata version 7.0 was used for the analysis.

RESULTS

After six months of treatment, 56 subjects continued with the program. Out of the 22 that abandoned the research (all female), 2 became pregnant, 1 moved out of the State and 1 had to go through a major surgery. The demographic, social and economical characteristics and the study group among those who abandoned the study were similar to those of the subjects that remained (data not shown).

Out of the total number of subjects that were in the beginning of the study, 5 were male (3 in group A and 2 in group B). The mean age of the subjects between the control and intervention groups was 35.36 (7.85) and 36.59 (7.31) years, respectively.

Initially, the groups did not present differences as to the anthropometric and biochemical variables. Both groups showed a significant decrease in weight, and consequently in their BMI, in the third and sixth month of follow up. However, weight loss in group B was higher than in group A (Table 3). Upon analyzing the mean values of the waist circumference, it was verified that group A presented a significant reduction only in the sixth month, while group B showed that reduction already in the third month. Fatty mass percentage results, showed only for female group, were significantly reduced for both groups ($p < 0.05$). Group B presented higher reduction of fat, but no clinical or estatistical signifiacnce was achieved.

Figure 1 shows the percentage mean of weight loss according to treatment group. In the first treatment month there was no difference in the percentage of weight loss between the groups. As of the second month, group B presents a more enhanced weight loss. As of the fourth month this difference shows to be significant ($p < 0.05$).

At the end of the treatment, 25.0% of the patients of the group B presented a weight loss higher than 10% of the initial weight, whereas in group A none of the patients presented a percentage of weight loss equal or higher than 10%. In both groups, 35.7% of the patients lost between 5 and 10% of the initial weight and 32.1% of the study group and 50.0% of the control group lost between 0 and 5%. Four patients of group B gained, in average, 1.37% (0.78) and two patients of group A gained, in average 0.75% (0.64).

There was a higher reduction in the biochemical variables in the first three months, in both treatment groups (Table 4). Comparing the triglycerides, LDL-cholesterol and glucose levels, between the beginning and after the three and six months of treatment, there was a significant reduction in the individuals only in group B. It is observed that as to insulin, group B was the only one to present a significant reduction in the third month.

TABLE 3
Mean (SD) changes in anthropometric measures at beginning, after three
and six months of treatment

		Initial	Third Month	Sixth Month
N° of patients	Group A	36	31	28
	Group B	42	36	28
Weight (kg)	Group A	78.11 (11.29)	75.61 (12.91)*	74.62 (12.28)*
	Group B	80.53 (13.34)	74.71 (11.98)*	73.11 (12.93)*
Weight loss (kg) §	Group A	—	-2.72 (2.10)	-3,69 (3.10)
	Group B	—	-4.32 (3.51)	-7,16 (4.85)
IMC (kg/m ²)	Group A	29.77 (3.03)	28.82 (3.36)*	28,42 (3.16)*
	Group B	29.55 (3.20)	27.93 (3.10)*	26,94 (3.12)*
Waist (cm)	Group A	89.96 (11.42)	88.01 (10.31)	86.14 (10.19)*
	Group B	92.31 (11.74)	84.61 (8.82)*	83.41 (9.18)*
Hip (cm)	Group A	108.46 (6.78)	104.51 (7.15)*	104.77 (6.76)*
	Group B	111.39 (7.97)	104.03 (7.79)*	104.03 (8.77)*
Body Fat (%)	Group A	37.57 (5.35)	35.96 (6.25)*	34.80 (6.31)*
	Group B	37.55 (5.52)	33.81 (6.01)*	33.42 (5.37)*

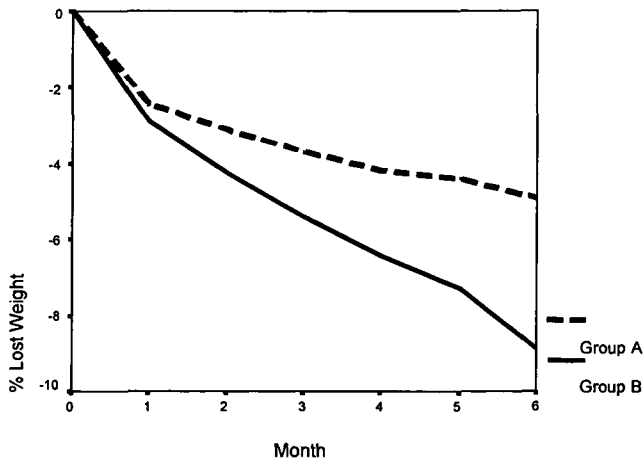
Data are represented by means and standard deviation N(SD). * T-student test compared with first observation.
§ GEE: treatment effect (p<0.001).

TABLE 4
Biochemical measures at beginning, and after three and six months of treatment

		Initial	Third Month	Sixth Month
Cholesterol	Group A	201.53 (43.20)	174.46 (36.04)*	187.96 (33.07)*
	Group B	193.81 (33.03)	168.14 (31.38)*	179.39 (26.79)*
HDL-cholesterol	Group A	53.72 (14.94)	50.71 (13.75)	53.39 (13.60)
	Group B	54.12 (13.40)	49.69 (10.66)*	54.68 (13.26)
LDL-cholesterol	Group A	123.39 (42.20)	107.00 (31.95)*	114.46 (31.38)
	Group B	114.34 (31.05)	99.25 (29.33)*	107.14 (21.36)*
VLDL-cholesterol	Group A	25.61 (15.82)	20.22 (10.25)*	20.11 (9.34)*
	Group B	22.19 (10.26)	17.61 (7.95)*	17.57 (10.50)*
Triglycerides	Group A	117.61 (64.37)	100.83 (51.13)*	101.00 (46.74)
	Group B	110.61 (51.54)	88.19 (39.83)*	87.82 (52.09)*
Glucose	Group A	90.97 (8.91)	84.09 (9.36)*	89.96 (13.39)
	Group B	88.57 (8.54)	84.61 (8.46)	85.10 (7.38)*
Insulin	Group A	10.53 (4.65)	10.21 (5.22)	9.45 (4.23)
	Group B	10.47 (6.52)	7.43 (3.27)*	8.33 (4.60)

Data are represented by means and standard deviation N(SD). * paired t-student test with initial data.

FIGURE 1
Percentage average of initial weight change during 6 months of treatment, in group A (control) and group B (intervention)



There was a significant change of relative loss weight throughout time, in the GEE model ($p < 0.05$).

DISCUSSION

Obesity treatment, by means of dietetic intervention and physical exercises, not always presented positive results, due to a high rate of individuals that either give up or do not comply with the several treatments. Another aspect that has drawn attention in weight loss programs is the difficulty that many individuals experiment in keeping their weight for a long period (14). This fact seems to be connected to lack of encouragement a low self-esteem.

In the present study, two groups (study and control groups) were followed up for six months. Both received the same dietetic guidance, but the study group was oriented to use a food substitute in the breakfast and in other meal during three months. From the third to the sixth month both groups started to use food substitutes in one of the major meals. It was observed that in the first month of treatment, that both groups presented similar decrease of body mass, an average of 3% of the initial values. It was concluded that all patients were highly motivated and eager to reduce energy intake. After this initial observation, treatment group presented a significant decrease of weight and after three months, this was a two fold decrease as compared to control group: (-2.72 (2.1) x -4.32 (3.5)). As of the second intervention period, the percentage of weight loss was significantly higher in the study group than in the control group (Figure 1). These results confirm those of other studies that evaluated the effect of a hypocaloric diet combined with the use of food substitutes for different periods.

Ditschuneit et al. (8) in a research conducted with a protocol with very similar design as ours, but with larger follow up, showed similar data. The average of weight loss in the first three months in the weight of the group that used food substitute was 7.1 (3.5) kg and in the control group was 1.3 (2.2) kg. An analysis conducted on studies on the efficacy of food substitutes use in weight loss programs showed that individuals that used food substitutes presented a more significant weight loss than those that only had a conventional nutritional guidance, and the average difference was 2.54 to 3.01 kg between the two groups in the first three months (15).

One of the advantages of using food substitutes is the control of caloric intake, once the individual only consumes a certain amount of calories. Another benefit is the composition of those products, because besides vitamins and minerals, they also have fibers that increase the feeling of being satisfied.

The emphasis is the program proposed in this study. Both groups had nutritional follow up every fifteen days, by nutritionists and were encouraged to carry out frequent physical activities. Therefore, the proposal is to adopt a healthy life style, by means of a balanced and hypocaloric diet and physical exercises, using food substitutes.

Upon analyzing the biochemical profile, both groups presented positive results. This can be seen as a result of the significant weight loss, once a weight loss of 5 to 10% of the initial weight is associated with improvement in metabolic profile (16). The difference in the lipid profile between the two groups was that in the study group there was a significant difference between the levels at the beginning and at the end of the six months for triglycerides and LDL-cholesterol, whereas in the control group this difference was observed only in the third month. This result might be a result of the mean values relatively normal of the lipid profile variables presented by both groups at the beginning of the study.

Ditschuneit et al. (17) evaluated the impact of the caloric restriction using food substitute on the lipid profile and verified that there was a significant reduction in triglycerides, only in the group that used food substitute in the third intervention month. The mean weight loss in this group was 7.8 (3.7) % of the initial weight. Another study that evaluated the metabolic profile of individuals that used food substitutes showed that the improvement of the lipid profile took place mainly in those individuals with total cholesterol higher or equal to 220 mg/dL and that presented weight loss of more than 5% of the initial weight (9).

As to insulin, it was verified that the study group was the only one to present a decrease in the mean values in the first three month. This result might be associated to a larger reduction in the waist circumference, also observed in this group, in the third month (control group: -1.95 cm; study group: -7.7 cm). Rice et al. (18) in a study conducted with obese men observed that abdominal fat reduction was critical

to improve sensitivity and reduce insulin plasma levels.

Throughout the study, the only manifestation of side effects that could be associated to product use was a transitory elimination of flatus, which discontinued after two weeks of drug usage. Both in the control and in the study group there was a significant change of life styles, with a gradual increase of physical activity and reduction of body measures. In an individual and qualitative analysis of attitude changes, all the patients mentioned incorporation of new types of food to their diet, reduction in fried food, chocolate and sweets consumption, and, at the same time, they mentioned a major change in the family dynamics. Even with not much significant weight loss, there was a change in the type of clothing, social and sexual activity, with more acceptance by the family and social group, regardless of the analysis group. Nutritional guidance programs, with logistics and situational support for daily situations are essential for those attitude changes

As seen in many developed and developing countries, Brazil is going through a nutritional transition, with a wide increase in obesity prevalence.

Nonetheless, obesity treatment presents high rates of lack of commitment, with patients continually dropping of. Using a food substitute, helping them to daily plan their meals, has proved to be very satisfactory during this study, with a high acceptance of product and of the entire nutritional program.

In conclusion, the use of food substitutes together with a balanced, hypocaloric diet, and the change in food habits proved to be efficient in weight loss for Brazilian, overweighted individuals, being a good alternative for overweight and obesity follow up.

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