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Efficacy of Healthy Weight Loss Program in Obesity Treatment: Croatian Experience

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A B S T R A C T

We evaluated the efficiency of a six-month outpatient weight loss treatment program combining healthy diet, fat reduction, psychological counseling, exercise, and orlistat treatment, by measuring body weight and levels of cardiovascular risk factors in 476 subjects with BMI over 30 or 28 with increased blood pressure, cholesterol, and sugar at the baseline and at the end of program. After four weeks of adjustment to a mild low-calorie diet (1600 kcal/day) and counseling, subjects started receiving orlistat (120 mg TID). The mean weight loss after 6 months was 10.9%. Systolic pressure dropped by 6.7%, diastolic by 4.2%, fasting blood glucose by 10.1%, and total cholesterol by 9.8%. Only 9 subjects (7.8%) poorly tolerated the treatment. More men than women were able to maintain the achieved weight loss six months after the program (70.6% vs. 58.3%, respectively). The healthy weight loss program was an efficient approach to obesity treatment.

***Key words**: obesity, weight loss program, orlistat, Croatia*

Introduction

According to the World Health Organization, obesity has assumed epidemic proportions and become the leading public health issue[1]. Excessive weight is an important risk factor for hypertension, hyperlipidemia, type 2 diabetes, some types of malignancies, and other diseases[1–3]. Prevalent data on Croatia are not consolidated, but according to one comprehensive study, 79.2% of men and 49.9% of women have a body mass index (BMI) >25, and 31.1% of men and 15.2% of women have a BMI >30[4], whereas the standardized death from cardiovascular diseases in 2001 was 91.7 per 100,000 population[3].

Excessive body weight is an enormous health issue, but still seems to be neglected in medical practice[5,6]. National cardiovascular disease prevention strategies in most countries strongly support programs introducing healthy lifestyle as the most cost-effective method in reducing cardiovascular morbidity and mortality[7,8].

Use of drugs in obesity treatment is not advised in patients with the BMI <28 unless they suffer from conditions caused by increased blood lipids, blood sugar, and hypertension[6]. Lipase inhibitor, orlistat, accompanied by a mildly hypocaloric diet helps reduce calories[6–12]. In addition, it reduces blood lipids, helps control glycemia, reduces insulin requirements, and helps normalize blood pressure[10,12]. Prevention of cardiovascular risks should therefore include reduction of weight, waist circumference, BMI, and hyperlipidemia and hyperglycemia, which are proven to be associated with high-fat diet. In other words, by reducing fat intake and absorption, such treatment algorithms can produce a beneficial domino-effect.

Behavioral approach to obesity treatment that aims at changing eating habits and lifestyle has been widely used[13]. When combined with pharmacological treatment, it improves the weight loss[14,15]. Our outpatient Healthy Weight Loss Program for obesity treatment is one of such comprehensive approaches to obesity treatment. The aim of this prospective study was to evaluate the efficacy, safety, and tolerability of the program and to evaluate the reduction in cardiovascular risk factors associated with weight loss and use of a lipase inhibitor.

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Subjects and Methods

Subjects

All subjects who attended the initial Healthy Weight Loss Program lectures about obesity, which has be organized by authors, at an out-of-hospital center in Rijeka were eligible for the study. To be included in the study, the subjects had to apply for participation in the program, be aged between 18 and 65, and have a BMI over 30 or BMI over 28 and increased cholesterol, blood pressure, and sugar. Of 900 who appeared at the initial lectures, 725 decided to participate in the weight-loss program, but only 627 went through a four-week period of adjustment to a mild low-calorie diet and were included in the study. Subjects who have a history of significant cardiac, renal, hepatic, or gastrointestinal disorders were excluded. Women were also excluded if they were pregnant or lactating. After the adjustment period subjects were included in a six-month Healthy Weight Loss Program and required to adhere to diet and attend workshops at an out-of-hospital center in Rijeka. However, during the program period 151 subjects withdrew, and 476 subjects completed the study (Figure 1). The mean age of subjects was 51.6±13.9 and there were almost twice as many women as men.

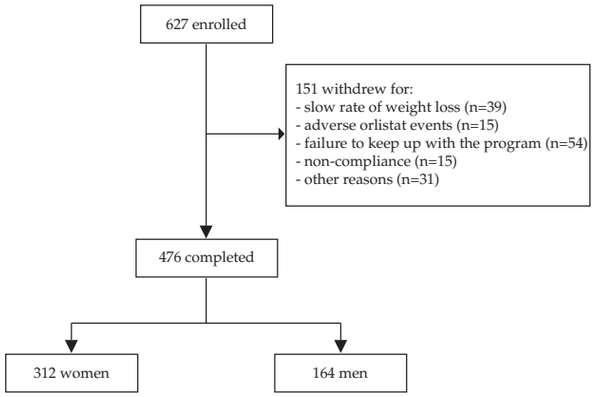

Fig. 1. Flow diagram of study participants.

Method

The Healthy Weight Loss Program consisted of education about healthy weight loss, counseling, use of a lipase inhibitor orlistat, and low-fat and low-calorie diet. Educational part included workshops organized by the study authors, general practitioners, internal medicine physicians, pharmacists, nutritionists, psychiatrists, and sports medicine specialists, who were all part of the Healthy Weight Loss Program. The workshops were interactive and included lectures and discussions on reasons for obesity, its complications, and treatment possibilities from healthy diet and regular exercise to pharmacotherapy. All study candidates received educational materials and a weight loss guide *Take Control Over Your Body Weight*[16]. Data on body height, body weight, waist circumference, BMI, blood parameters, and blood were collected at baseline. Body weight and BMI were also measured after three and six months, whereas blood parameters and blood pressure were measured only at the end of program, i.e. after six months. Blood samples were tested in the central laboratory of Thalassotherapy Center in Opatija, a town near Rijeka.

During the six-month follow up, the subjects were on a mild low-calorie diet containing no more than 30% of fat. After four weeks of a low-calorie diet (1600 kcal/day, three meals a day) and psychotherapeutic and nutritional counseling, subjects started receiving orlistat (120 mg 3 times a day), a lipase inhibitor that reduces fat absorption in the gastrointestinal system by 30%[9,10]. No appetite suppressors were allowed during the study. Monthly interviews with the subjects addressed the issues related to the diet, everyday stress, physical activity, and obstacles to weight loss and maintenance. Particular attention was given to the analysis of failed attempts to lose weight. The subjects were allowed to bring along friends or family members to the interview. All subjects maintained a diary in which they regularly recorded all data related to the diet, physical activity, and difficulties encountered. The follow up included a questionnaire for all subjects with the following information to be filled in: age, sex, accompanying diagnoses, lifestyle, body height, body weight, body mass index, waist circumference, blood pressure, triglycerides, cholesterol, glycemia, undesirable effects, subjective perception of treatment success. These data were filled in on every monthly visit over the six-month program. All subjects received detailed information about healthy diet, physical activity, and weight control program. Six months after the orlistat therapy had finished, the subjects were contacted by phone or mail to inquire about their body weight and satisfaction with the weight loss program.

Statistical analysis

Data were presented as mean values with standard deviations (±SD) and analyzed with Students t-test. P values <0.05 were considered statistically significant. All statistical analyses were performed with SAS© System for Windows, version 8.2 (SAS Institute Inc., Cary, NC, USA).

Results

The investigated parameters that were measured after 3 and 6 months of the study showed a significant decrease in comparison with baseline values in all subjects (Table 1). The mean weight loss was 5.7 ± 3.5 kg (6.3%) after 3 months and 9.9 ± 6.1 kg (10.9%) after 6 months ($P<0.001$ for both; Table 1). After 6 months of the program, systolic pressure decreased by 6.7%, diastolic pressure by 4.2%, fasting blood glucose by 10.1%, and total cholesterol by 9.8% on average ($P<0.001$ for all; Table 1). After six months, all parameters significantly decreased in both men and women. Although the decrease in all parameters except cholesterol was more pronounced in

TABLE 1
PARAMETERS MEASURED IN 476 SUBJECTS INCLUDED IN THE HEALTHY WEIGHT LOSS PROGRAM AT BASELINE AND AFTER 3 AND 6 MONTHS

Parameter	Mean±SD		
	baseline	3 months*	6 months*
Age (years)	51.6±13.9		
Waist circumference (cm)	102.5±14.2		92.5±13.6
Height (cm)	168.5±8.9		168.5±8.9
Weight (kg)	90.4±16.5	84.7±15.1	80.5±14.1
Body mass index	31.8±5.0	29.8±4.6	28.3±4.3
Systolic pressure (mm Hg)	144.0±21.6		134.3±12.1
Diastolic pressure (mm Hg)	87.9±11.0		84.2±7.1
Blood glucose (mmol/L)	5.9±1.8		5.3±1.2
Cholesterol (mmol/L)	6.1±1.1		5.4±0.7

*P<0.001 for each measured parameter in comparison with baseline values, *t*-test.

men than in women, there were no statistically significant differences between the sexes (Table 2). Blood sugar was the only parameter that decreased significantly more in men than in women (0.9±1.2 vs 0.5±0.7, respectively, P<0.001). Men lost 12.1±7.8 kg on average, whereas women lost 8.8±4.6 kg. BMI decreased correspondingly, i.e. by 3.9±2.5 for men and 3.2±1.7 for women. While taking orlistat, 57.4% of subjects were able to change their dietary habits (reduced caloric intake and reduced percentage of fat). Undesirable effects of orlistat were recorded in 50.4% of subjects. Most common complaints were stool-related, as 41.4% subjects complained of steatorrhea, 19% of irregular stool, and 27.6% of other stool-related problems. Also, 9% complained of thirst and 12% of flatulence.

Nearly all subjects (95.7%) had attempted to lose weight before entering the Healthy Weight Loss Program, mostly by low-calorie diets (24.8%), changes in dietary habits (23.9%), over-the-counter weight loss drugs (20%), exercise (15%), and acupuncture (15%). Most subjects expressed preference for lipase inhibitor over earlier weight loss attempts, 20.7% did not compare the earlier and current treatment, 25.2% stated that the treatments could not be compared, and 21.6% believed that the lipase inhibitor treatment was more successful and that the diet was normal insofar as it did not require any particular effort to adhere to it (16.2%).

There were 151 subjects who did not complete the program (Figure 1). The most common reasons for withdrawal were inability to keep up with the program and attend consultations with study physicians (35%), slow rate of weight loss (25%), non-compliance (10%), and diarrhea as an adverse effect of orlistat (10%).

Six months after the discontinuation of lipase inhibitor, 60.4% of subjects said they maintained the weight achieved by the end of the program. As many as 98.1% of subjects said that they felt healthier after having lost weight. A little over the half of the subjects (53.5%) read all educational materials received in the weight loss program. A smaller number (15.0%) consulted the web pages of the weight loss program and 23.6% consulted the study doctor over the phone.

The weight loss program with lipase inhibitor received high scores from the subjects. On the scale from 1 (poor) to 5 (excellent) as many as 89.4% considered the use of lipase inhibitor very good or excellent, and 83.8% expressed the same level of satisfaction with the whole weight loss program. More men than women were able to maintain achieved weight loss after lipase inhibitor treatment (70.6% vs. 58.3%, respectively). Women gave a slightly higher mean score to the lipase inhibitor treatment than men (4.45 vs. 4.30, respectively), whereas the

TABLE 2
PARAMETERS MEASURED IN MEN AND WOMEN INCLUDED IN THE HEALTHY WEIGHT LOSS PROGRAM AT BASELINE AND AFTER 3 AND 6 MONTHS

Parameter	Mean±SD					
	Men (n=164)			Women (n=312)		
	baseline	3 months*	6 months*	baseline	3 months*	6 months*
Age (years)	53.8±13.8			50.5±13.9		
Waist (cm)	110.3±13.4		100.37±12.8	98.4±12.8		89.54±12.1
Height (cm)	175.9±8.4		175.9±8.4	164.6±6.3		164.6±6.3
Weight (kg)	101.4±17.5	94.5±15.7	89.3±14.5	84.6±12.7	79.6±11.9	75.8±11.5
BMI	32.9±5.6	30.6±5.1	28.9±4.6	31.2±4.6	29.4±4.3	28.0±4.1
Systolic pressure (mm Hg)	147.7±19.6		136.4±11.8	142.2±22.4		133.2±12.2
Diastolic pressure (mm Hg)	89.3±10.7		85.3±6.4	87.2±11.2		83.6±7.4
Blood glucose (mmol/L)	6.5±2.1		5.6±1.3	5.5±1.5		5.1±1.1
Cholesterol (mmol/L)	6.1±1.1		5.4±0.7	6.1±1.1		5.4±0.7

*P<0.001 for each measured parameter in comparison with baseline values, *t*-test.

weight loss program received similar scores by both sexes. Nearly all subjects said that they would recommend lipase inhibitor treatment (96.5%) and the Healthy Weight Loss Program (96.0%) to their friends.

Discussion

According to our results, the six-month outpatient Healthy Weight Loss Program consisting of diet, lipase inhibitor orlistat, counseling, and education led to a significant weight and BMI reduction and decrease in cardiovascular risk factors in our subjects. Although half of subjects complained of orlistat side effects, they were overall very satisfied with the effects of the program. Almost two-thirds of subjects maintained the reduced weight six month after the program had finished.

The role of drug treatment of obesity is still open and inconclusive[6]. A great contribution to better understanding of the efficacy and safety of drug use in the treatment of obesity has come from a meta-analysis of different medications for obesity treatment, which showed that these drugs promote weight loss for at least 6 months when used along with a diet (and possibly other behavioral and exercise interventions)[18]. The amount of extra weight loss attributable to these medications is modest, <5 kg within a year, but it still may be clinically significant. Different comparative studies into weight-loss medication have shown that orlistat leads to weight reduction as effectively as other drugs[19] and that it is more effective in reducing cholesterol, triglycerides, and blood pressure than sibutramine[18,20].

Findings from Ireland, Sweden, and Switzerland point to the cost-effectiveness of obesity treatment with orlistat[21–23]. The base-case economic analysis revealed that the costs per quality-adjusted life year gained were substantial, which is the reason why orlistat treatment is being reimbursed through health insurance in Sweden and Switzerland to make it accessible to all who need it. An Irish study used economic modeling techniques to evaluate five clinical trials with 1386 subjects[22]. This model showed that patients receiving orlistat for 12 months had a mean weight loss of 11.6%, as opposed to 7.9% in placebo controls. Patients who lost over 5% of their baseline weight in the first three months, at the end of the trial achieved a loss of 15.5%; this has become the threshold for health insurance coverage for orlistat treatment. Even though sophisticated models such as this are not available in Croatia, a comparison of data used in calculations suggests that we would arrive at a similar conclusion.

There is still the question of the long-term effects of these drugs on health. Only a few studies attempted to evaluate the effects of long-term weight loss programs on health. One of these studies that evaluated long-term effects was XENDOS, a randomized placebo controlled study of orlistat in combination with lifestyle changes which enrolled over 3000 obese patients (mean BMI 37kg/sqm), of whom 21% were glucose-intolerant[24]. The four-year follow up showed that orlistat-treated patients lost more weight than placebo controls and had a 37% lower risk of diabetes incidence. Even though only 52% of orlistat-treated patients and 34% of placebo recipients completed the treatment, this study corroborates the hypothesis that long-term orlistat treatment may result in a loss of body weight and help reduce obesity-related health problems.

Another question that has remained unanswered is a relative efficacy of obesity drugs. This also raises the questions of whether a combination of drugs could result in greater weight loss than single drugs[25] and whether the use of these drugs in combination with a more aggressive lifestyle changes and low-calorie diet would be more efficient than mild low-calorie diet. And last but not the least, there is the question of optimal duration of treatment. None of the randomized controlled studies have offered more definitive answers to these questions, but have left them to future clinical trials.

Some physicians believe that overweight patients have to take medications for weight loss, which makes overweight a chronic disease, similar to hypertension[26,27]. In that case, new information on long-term (longer than 12 month) efficacy and safety of obesity drugs is needed. The XENDOS study of the efficacy and safety of orlistat has so far been the longest such study of obesity drug treatment[24].

Most studies in obesity treatment have been conducted by specialists in hospitals, even though this issue requires a broader approach, including outpatient follow-up by family physicians[28,29]. Our assumption was that a comprehensive outpatient weight loss program would result in a statistically and clinically significant loss of weight and decrease in cardiovascular risks. The results of our study showed a significant decrease in body weight, BMI, systolic and diastolic blood pressure, fasting blood glucose and total blood cholesterol in both men and women included in the Healthy Weight Loss Program. Our results are in accordance with previous studies that showed a behavioral approach to be successful in the treatment of obesity[28–38]. A comprehensive review of studies that followed long-term effects of weight loss on hypertension between 1966 and 2001 has shown that a 10-kg weight loss decreased systolic and diastolic pressure by 4–6 mm Hg[32]. In our subjects who lost 5–10%, the values of blood pressure, lipids, and glucose normalized and they themselves reported feeling healthier.

Multidisciplinary approach not only enhances the effects of pharmacotherapy, but also helps maintain reduced body weight through a newly adopted lifestyle. The results and experiences from our Healthy Weight Loss Program confirm that treatment of obesity should progress gradually and that the goals set should be realistic to avoid disappointment in patients and counter-effects of quick weight loss. We believe that family physicians and pharmacists should have a more important role in obesity treatment. They would be ideal partners in designing and conducting similar healthy weight loss programs, as they are the first to be approached by overweight patients who seek professional help. A number of

studies have confirmed that it is primary care where orlistat treatment programs are the successful form of treatment of obesity and prevention of serious clinical complications, including cardiovascular diseases[28,29,33–37].

There are several limitations to our study. First, there is a possibility of self-selection bias as subjects who attended the introductory lessons could freely decide whether or not to join the program. Second, the subject attrition rate was around 30%. The subjects dropped out from the program either during one month of adjustment to a mild low-calorie diet or during the program itself, but for different reasons. Further limitation is use of self-reported data on adherence to diet. However, the body weight was measured at baseline and at the end of the program and showed a significant decrease. The fourth limitation is use of self-reported data on maintenance of reduced weight during the follow-up six months after the program had finished. Nevertheless, the participants reported being satisfied with the results of the program.

In conclusion, our program of obesity treatment has been proven to be efficient not only in weight loss, but also in lowering high blood pressure, lipids, and sugar, all known risk factors of cardiovascular diseases. This suggest that reduced fat intake and absorption through food can help prevent obesity-related cardiovascular complications and reduce morbidity and mortality from cardiovascular diseases as well as prolong life and working life expectancy. For a definitive evaluation, our Healthy Weight Loss Program based on low-fat diet, reduced fat absorption from food, and education about healthy lifestyle needs to be continued and similar new projects started with a large sample for a longer study period that would definitely show if this treatment algorithm provides a good basis for control of cardiovascular risk factors. A project for prevention and treatment of obesity that would involve family physicians, pharmacists, and other interested parties from civil society to health insurance, pension funds, and government institutions would be able to properly address the issue of combating risk factors of the development of diabetes and cardiovascular diseases as the leading causes of morbidity and mortality today in developed and many developing countries.

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DJELOTVORNOST LIJEČENJA PRETILOSTI PROGRAMOM ZDRAVOG MRŠAVLJENJA: HRVATSKO ISKUSTVO

S A Ž E T A K

Procjenili smo učinkovitost šestomjesečnog ambulantnog programa mršavljenja temeljenog na kombinaciji zdrave prehrane s redukcijom prehrambenih masnoća, psihološkog savjetovanja, tjelovježbe i liječenja orlistatom. U studiju je uključeno 476 ispitanika s indeksom tjelesne mase (ITM) iznad 30 ili ITM iznad 28 uz razvijenu hipertenziju, hiperkolesterolemiju ili poremećaj glikemije natašte. Na početku i kraju programa mjerena je tjelesna težina i ispitivani čimbenici ukupnog kardiovaskularnog rizika. Nakon 4 tjedna niskokalorijske dijete (1600 kcal dnevno), uz odgovarajuće savjetovanje, ispitanici su započeli terapiju orlistatom u dozi od 120 mg. Pad tjelesne težine nakon 6 mjeseci iznosio je u prosjeku 10,9%, pad sistoličkog krvnog tlaka 6,7%, dijastoličkog 4,2%, glukoze natašte 10,1% i ukupnog kolesterola 9,8%. Samo devet ispitanika (1,89%) je imalo poteškoće u provođenju programa. Muški ispitanici su u odnosu na žene u značajnijem postotku održavali postignutu tjelesnu težinu tijekom idućih šest mjeseci (70,6% muškaraca, 58,3% žena). Primijenjeni program mršavljenja uspjesno je potvrdio svoju djelotvornost u liječenju pretilosti.