

THE EFFICIENCY OF THE 'HEALTHY WEIGHT REDUCTION PROGRAM' IN THE TREATMENT OF OBESITY

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SUMMARY – Obesity is a condition characterized by storage of excessive amounts of fat in the body. According to the World Health Organization, obesity has reached epidemic proportions and has become a leading public health issue. The increase in body weight causes numerous clinical complications and affects the quality of life, ability to work, and longevity of the patient. The treatment costs, direct and indirect, have become a substantial burden of healthcare systems. The etiology of obesity is complex and includes genetic factors, lifestyle, psychological factors, and, of course, high-fat diet. Fats are significant sources of calories, which are stored in the body in the form of fatty tissue. Typical human diet contains over 40% of fat, although the recommended maximum is 30%. Insufficient physical activity fosters the accumulation of adipose tissue. A sensible approach to the treatment should include moderate diets rich in carbohydrates, regular exercise, and pharmacological aid, if necessary. Weight loss programs offer a new multidisciplinary approach with a long-term goal to change the patient's lifestyle and to treat the illness and its complications. The aim of this pilot study was to assess to what extent intensive healthy diet education, psychotherapist's counseling, and exercise contribute to successful pharmacological treatment of obesity. Besides the psychotherapeutic and nutritional counseling, the Healthy Weight Loss Program relied on the treatment with orlistat, a representative of the new therapeutic group of lipase inhibitors, which selectively binds to the lipase enzyme in the gastrointestinal tract, thus preventing the fat digestion into simpler forms and reducing their absorption in the body by up to 30%. The analysis of the six-month program, which included 111 subjects, showed the comprehensive approach to therapy of obesity to have a statistically significant effect on weight control. The average weight loss was 12.5% of the baseline weight. Besides the weight reduction, the glucose metabolism improved, and blood pressure levels dropped by 5%. The subjects expressed satisfaction with the program and the results achieved. The analysis of the achievements confirmed the weight loss program based on education, psychotherapeutic counseling, and therapy with orlistat to be an efficient and reliable mode of obesity management.

Key words: *Obesity, drug therapy; Anti-obesity agents, therapeutic use; Body weight, drug effects*

Introduction

Obesity is defined as a condition characterized by excessive storage of fatty tissue in the body. The fat content in the total body weight in normal healthy men and women is 15%–20% and 20%–25%, respectively¹. According to the World Health Organization, obesity has assumed epidemic

proportions and has become a leading public health issue. Estimates point to 100 billion clinically obese persons worldwide^{1,2}. Croatia lacks reliable data, however, estimates suggest that 15% of male and 25% of female population are obese¹. The increase in body weight may cause numerous clinical complications which affect the quality of life, ability to work, and longevity of obese persons. The related treatment costs, direct or indirect, heavily weigh on national healthcare budgets. Reserved estimates based on data from several most developed countries suggest that the share of obesity treatment costs ranges between 3% and 8% in the

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total healthcare expenses³. Excess weight substantially facilitates the development of cardiovascular diseases, hypertension, hyperlipidemia, type 2 diabetes, some types of malignant tumors, and many other diseases. For example, the incidence of type 2 diabetes and hypertension is 2.9 times greater in obese than in normal population, whereas hyperlipidemia is 1.5 times more frequent in obese persons^{1,2}. Furthermore, it is a well known fact that successful weight loss is difficult to achieve, and frequent failures to attain this goal may lead to disappointment as much in patients as in healthcare workers. Obviously, success requires more effective treatment strategies. That is why it is important to understand the origin of obesity. Without knowing why and how people become obese, one cannot come up with a cost-effective treatment. The etiology of obesity is complex and includes genetic factors, lifestyle, psychological factors, and the last but definitely not the least, high-fat diet. Fats are a substantial source of calories which are stored in the body in the form of fatty tissue. The fat content in a typical human diet is over 40%, although the recommended maximum is 30%. A sensible treatment of obesity should therefore rely on moderate diet rich in carbohydrate, regular exercise, and pharmacological aid, where necessary.

Lipase inhibitors are a new generation of drugs for the treatment of obesity. They bind to the lipase enzyme and inhibit fat digestion into simpler forms, thus decreasing the absorption of dietary fat by up to 30%. This mechanism of action makes the lipase inhibitors more appropriate for long-term therapy than appetite suppressants, which affect the central nervous system³. However, pharmacotherapy should always come last. Therapy should begin with a lifestyle change, which includes healthier dietary habits, psychotherapeutic counseling, and regular exercise. As obese persons often seek support in their intent to lose weight from the people surrounding them, small therapy groups or programs for healthy loss of weight that combine psychotherapy, nutrition education and pharmacotherapy may strongly motivate the patients and serve as a general guideline to organized and counselled weight control.

Subjects and Methods

The investigation included 97 women and 14 men from the city of Zagreb, Croatia, aged between 22 and 55 years, whose body mass index exceeded 30 or 28 when combined with the increased risk from cholesterol, hyper-

tension, and diabetes. The study subjects are included in a 24-month multicenter prospective study covering the entire Croatia. These results are therefore to be viewed as temporary. The subjects entered the study through the 'Healthy Weight Reduction Program' launched by the authors. Branches of the program have been established in Zagreb, Split, Osijek and Rijeka by the respective offices of F. Hoffmann-La Roche Croatia. Body height, weight, body mass index, waist circumference, and blood sugar and triglycerides were determined in all study subjects. The subjects underwent a 6-month treatment with moderate hypocaloric diet containing less than 30% of fats. After four weeks of adjustment to the 1600 kcal daily diet and psychotherapeutic and nutritional counseling, the subjects were given treatment with the lipase inhibitor orlistat (Xenical®, F. Hoffmann-La Roche) with meal three times a day. Orlistat is known to reduce fat absorption in the digestive system by 30%. Study subjects took no appetite suppressors during the study and kept daily records of their diet and physical activity. Groups of ten subjects met every three weeks. The sessions served to discuss diet, everyday stress, physical activity, and other potential reasons that could hinder the progress of weight loss and control. Special attention was paid to the analysis of previous failed weight loss attempts. All subjects kept their diary regularly, recording all data about their diet, physical activity, and problems they faced in the course of the program. The follow-up questionnaire included information on the age, sex, diagnosed complications, lifestyle, height, weight, body mass index, waist circumference, blood pressure, blood triglycerides, blood cholesterol, glycemia, side effects, and personal evaluation of satisfaction with the treatment.

The questionnaire was distributed on each examination during the six-month study. The subjects were followed-up to see how successful they were in losing weight, whether they were regaining weight, and what was the effect of fat intake reduction on the risk factors associated with obesity. We analyzed the impact of the resulting risk factor modifications on the occurrence of obesity-related complications, on the quality of life, and on the subjects' satisfaction with therapy. Hypertension and impaired glucose tolerance and type 2 diabetes were diagnosed according to recommendations of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure⁴², and American Diabetes Association Expert Committee⁴⁵.

All subjects received detailed instructions concerning the diet, physical activity, and weight reduction program.

Over the six months of group work, education and exercise, we interviewed all study subjects on an individual basis and followed their progress in-between monthly sessions.

Results

Nine of 111 subjects quit the weight reduction program. They all stated that the reason for quitting was their inability to attend group sessions. The average body mass index of all study subjects was 32. Seventy-seven percent of the subjects joined the program on their own initiative, and 23% on an expert referral (by a physician or pharmacist/druggist). Fifty-seven percent of the subjects joined the program to improve their health, and 43% to improve their physical appearance. Health was the only reason for joining the program for men. Thirty-one percent of women and 55% of men were smokers. Hypertension was diagnosed in 18.55%, increased lipids in 20%, and elevated blood sugar in 14% of the subjects. The mean weight loss after the 6-month treatment was 12.75 kg or 12.5% of the baseline body weight. Waist circumference decreased by 9.7 cm on an average. Weight reduction by more than 5% and 10% of the baseline value was achieved in 73.5% and 47.5% of study subjects, respectively. Adipose tissue measurements confirmed that weight reduction was the result of fat tissue loss, especially around the waist. The analysis showed an improvement in blood lipids and glyceride profile in all subjects. Total blood cholesterol dropped by 14.5%. Systolic and diastolic pressure also dropped by 5%. The subjects expressed satisfaction with the program. Only 5% of them stated they were not satisfied with the rate of weight loss, and 98% referred to pharmacotherapy side effects as negligible. Ninety-six percent of the subjects recommended the Healthy Weight Reduction Program to all individuals experiencing problems with excess weight. Psychotherapy and nutrition education received particular acclaim and so did the group work. All this provides a basis for long-term control of body weight.

Discussion

According to some sources, 20% of the general population seek to reduce weight through a variety of diets and other activities. Yet, most attempts end in failure. To create an effective strategy to treat obesity, one needs to work

out all details, from the diagnosis and origin of the disease through effective therapy and change in the behavior/lifestyle. Epidemiological research has revealed a variety of factors favoring the development of obesity². One of the leading factors is the intake of foods rich in fat^{3,4}. Japan has the lowest food fat intake and lowest average body weight, whereas the United States food fat intake values and average body weight are among the highest in the world^{5,6}. Of 13 studies⁷⁻¹⁸ conducted by Lissner and Heitmann, 11 showed a statistically significant correlation between fat intake, and one or more signs and symptoms of obesity. The body mass index was observed to decrease with the growing participation of carbohydrates¹⁸. The correlation between the percentage of calories from fat and body mass index was equally observable in children and adults¹⁹⁻²³. Experimental data support the epidemiological evidence of association between the high-fat diet and obesity^{23,24}. The consumption of high-fat and high-carbohydrate diets of equal energy value by infants did not produce differences in weight gain. However, when the energy value of high-fat diet was higher, the infants who consumed it received more calories and gained more weight. Human predisposition to the foods with high fat content probably is in part genetic and in part a learned habit. Genetic predisposition to the foods rich in fat was confirmed by the finding that neonates sucked high-fat milk with more vigor than low-fat milk. Sucking babies showed a similar preference for simple sugars^{25,26}. Weight gain associated with high-fat diet may be the consequence not only of increased calorie intake, but also of metabolism differences after absorption. Fat calories lead to greater weight gain than calories from carbohydrates or proteins, as fats are more likely to be stored in the body than to burn. The limitation of the fat content in the diet to 30% led to changes in fat metabolism and to increased energy consumption, which in turn showed that the new fat:carbohydrate ratio might restore a healthy balance between all nutrients. The authors conclude that obesity may be viewed as a carbohydrate deficiency syndrome, and that the increase in carbohydrate dietary content at the expense of fat might be an appropriate dietary part of the therapeutic strategy^{27,28}.

With obesity and related clinical complications in mind, a decrease in the percentage of fat in the diet would do much good to the community. It would bring substantial savings to the healthcare and pension funds. Health benefits at the level of the whole population are relatively easy to achieve by a modest cut in the share of dietary fat. No doubt, increased physical activity would also be ben-

eficial²⁹. However, this modest extent of changes would perhaps be insufficient to help distinctly obese persons whose life is directly threatened by excess weight and who need the aid of pharmacotherapy. Low-fat diets with limited calories seem to answer the question for most patients seeking to lose weight. To achieve a sustained, long-term weight reduction, persons prone to obesity should adopt a new lifestyle with low-fat diet³⁰⁻³⁷. Drastic reductions are to be avoided and pharmacotherapy should be administered sensibly. Weight reduction achieved by low-fat diets is usually modest but sufficiently beneficial for health. Evidence show that a 5% weight loss substantially reduces the risk of clinical complications. As a rule, obese patients with a history of complications, most often hypertension and cardiovascular diseases, are recommended to lose weight, however, this goal often turns to be too arduous and too high for both obese patients and their physicians.

The history of treatment of obesity points to side effects of drugs that suppress appetite through inhibitory mechanisms in the central nervous system and yield short-term results due to the generally very limited period of administration³⁷⁻⁴¹. A completely new approach to the treatment of obesity has been introduced with the advent of the lipase inhibitor orlistat (Xenical®, F. Hoffmann-La Roche), which in combination with a moderate low-fat (below 30%), hypocaloric (20% deficit) diet additionally reduces fat absorption and leads to a more efficient long-term control of body weight^{40,41}. However, pharmacotherapy is only a temporary or supplementary measure, whereas a comprehensive treatment program should include help in adopting healthy eating habits and regular exercise to achieve long-term results. Psychotherapeutic counseling plays a special role in the treatment; it is well known that excessive eating is a way of escape from the stress which life has in stock for us every day. Foods rich in fat give a pleasing sensation that restores good mood and are the reason for substantial weight gain in persons who resort to them. Group work opens a way to the solution through sharing with the people experiencing similar problems and learning to live a healthier life. The program starts with setting an achievable goal with each participant, and proceeds with gradual change of the diet, intensified physical activity, and psychosocial support. Pharmacotherapy facilitates the implementation of the program and strengthens the motivation and resolution of all participants. As the obesity problem is mostly associated with excessive fat content in the diet, orlistat as a lipase inhibitor perfectly blends in the program.

Our results are preliminary, but the pilot study has already indicated that our weight reduction program is more

successful than pharmacotherapy alone. In other words, the administration of orlistat in combination with nutrition education, psychotherapeutic counseling, and disciplined physical activity led to more successful weight control in the long run. Group work creates an affirmative atmosphere of mutual support, which facilitates the introduction of a healthier lifestyle and achievement of long-term weight control. The efficiency of orlistat in reducing body weight through inhibition of fat absorption and in reducing risk factors such as high blood lipids, sugar and pressure, in combination with healthy eating habits and regular physical activity as the basic tenets of the Healthy Weight Reduction Program provide a good model for competent and organized long-term therapy of obesity. Previous studies report on an average 6-month weight loss of 6.1%-7.4% with sibutramine and 8.5%-10% with orlistat, whereas our results (12.5%) suggest that a comprehensive approach increases the efficiency of pharmacotherapy and, which is even more important, discourages regaining of weight due to the lifestyle change even after pharmacotherapy has been discontinued. The satisfaction of our subjects with the program and the results achieved are particularly important, as they suggest that the program might work as a long-term solution in the treatment of obesity.

Conclusion

Obesity has become one of the leading problems for healthcare workers, having assumed epidemic proportions and causing numerous complications that adversely affect the quality of life and longevity, and impose substantial financial burden on healthcare funds. Croatia also shows a greater share of obese persons among patients suffering from hypertonia and diabetes than of those with normal body weight. Obese persons often use sick-leave and retire earlier through disability retirement programs. Many obese persons feel socially insecure and rejected. One should never forget that obesity is a chronic disease requiring life-long treatment in most cases. At the same time, unsuccessful treatment induces a feeling of futility of the endeavors for both patients and physicians. Well designed programs, however, may help patients live longer and better. Disciplined low-fat diet rich in carbohydrates and the aid of drugs when necessary seem to provide the best answer for obese persons who want to lose weight and to reduce the risk of cardiovascular diseases and other life-threatening clinical complications. The treatment based on physiological principles gives best hope for long-term success in this rather challeng-

ing, yet solvable healthcare issue. Weight reduction programs, which include group therapy and teach people how to live a healthier and better life are a feasible option in a competent and organized approach to the treatment of obesity. That is why the pilot project described should live on and eventually show long-term effects of a multidisciplinary approach to the treatment of obesity in a statistically relevant population sample.

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Sažetak

UČINKOVITOST ŠKOLE ZDRAVOG MRŠAVLJENJA U LIJEČENJU PRETILOSTI

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Pretilost je stanje prekomjernog nakupljanja masnog tkiva u organizmu. Prema mišljenju Svjetske zdravstvene organizacije, pretilost je poprimila epidemijske razmjere i postala vodeći problem javnog zdravstva. Zbog povećane tjelesne težine nastaju brojne kliničke komplikacije koje smanjuju kvalitetu života, radnu sposobnost i životni vijek oboljelih. Izravni i neizravni troškovi liječenja pretilosti predstavljaju velik teret za proračune zdravstvenih sustava. Etiologija pretilosti je složena i uključuje genetske čimbenike, životne navike, psihološke čimbenike, ali nedvojbeno je da jednu od ključnih uloga ima masna prehrana. Masti čine značajan izvor kalorija koje se uskladištavaju u organizmu u obliku masnog tkiva, a tipičan sastav ljudske hrane sadrži više od 40% masti, iako se preporuča da udio masti iznosi najviše 30%. Istodobno premala tjelesna aktivnost pomaže gomilanju masnog tkiva. Razborito liječenje pretilosti temelji se stoga na umjerenj dijeti bogatoj ugljikohidratima, redovitoj tjelesnoj aktivnosti, uz farmakološku potporu kada je to potrebno. Škole zdravog mršavljenja predstavljaju potpuno nov multidisciplinarni pristup koji ima za cilj promjenom životnih navika dugoročno riješiti problem pretilosti i njenih komplikacija. Cilj ovoga probnog istraživanja bio je utvrditi u kojoj mjeri intenzivna izobrazba o prehrani, psihoterapijska potpora i redovita tjelesna aktivnost pojačavaju učinak farmakoterapije. Kao sastavni dio škole se, uz psihoterapijske i nutricionističke savjete, primjenjivao orlistat, predstavnik nove terapijske skupine inhibitora lipaze, koji djeluje u gastrointestinalnom sustavu selektivno se vezujući za enzim lipazu, čime sprječava razgradnju masti do jednostavnih oblika i na taj način smanjuje apsorpciju masti unesenih hranom za 30%. Analiza šestomjesečnih rezultata škole, u koju je bilo uključeno 111 ispitanika, pokazuje da ovakav cjelovit pristup u terapiji pretilosti statistički značajno poboljšava kontrolu tjelesne težine. Prosječni gubitak tjelesne težine iznosio je 12,5% početne tjelesne težine. Uza smanjenje tjelesne težine statistički je značajno učinkovito regulirana lipidemija, poboljšana je metabolizam glukoze, te su snižene vrijednosti krvnog tlaka za 5%. Ispitanici su iskazali veliko zadovoljstvo programom škole, kao i postignutim rezultatima. Navedena analiza i dobiveni rezultati potvrđuju da škola zdravog mršavljenja utemeljena na izobrazbi, psihoterapijskoj potpori, u kombinaciji s orlistatom predstavlja učinkovitu i sigurnu terapiju pretilosti.

Ključne riječi: Pretilost, lijekovi; Sredstva protiv pretilosti, terapijska primjena; Tjelesna težina, učinak lijekova