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ORIGINAL ARTICLE

ORLISTAT AND PHENTERMINE IN WEIGHT LOSS IN SELECTED CZECH POPULATION

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Summary

Aim: To describe effectiveness of orlistat and phentermine in soldiers of the Armed Forces of the Czech Republic.

Methods: In ambulatory patients, some anthropometric and biochemical parameters were compared before administration with 120 mg of orlistat three times a day or 15 mg of phentermine once a day. The same parameters were compared after a three-month therapy. This group included 289 patients (238 males and 51 females) who were administered the same dose of orlistat or phentermine for the entire period of time.

Results: Statistically significant weight loss in both genders, on average by 4.6 ± 4.2 kg in males and by 5.3 ± 4.3 kg in females, was observed in patients taking orlistat within three months. Statistically significant weight loss, on average by 6.5 ± 6.0 kg in males and by 5.2 ± 4.3 kg in females, was also observed in patients taking phentermine for the same period of time. As for monitored biochemical parameters, a decrease of total cholesterol, HDL cholesterol and glucose at a statistically significant level ($p<0.05$) was observed in the group of females, the same statistically significant decrease, but in triglycerides, was proved in the group of males. Then a decrease of total cholesterol and increase of HDL cholesterol at a statistically significant level ($p<0.001$) was observed in the group of males.

Conclusion: We can state that in our patients we have proven a positive effect of orlistat or phentermine substitution on their weight reduction.

Key words: Anti-obesity agents; Pharmacotherapy of obesity; Weight reduction; Health support; Czech Armed Forces

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INTRODUCTION

Currently, obesity is considered to be the most frequent metabolic disease worldwide. This disease occurs due to changing living conditions and lifestyle that has resulted in a positive energy balance. Despite continuous development in treatment of obesity its

prevalence is constantly increasing, thus preventive and intervention procedures targeted not only at individuals, but also at separate population groups are necessary [1,2,3]. Anthropometric parameters in professional soldiers demonstrate the prevalence of overweight and obesity in the Armed Forces of the Czech Republic (ACR). Some of the biochemical markers of a cardio-metabolic risk such as total cholesterol, LDL cholesterol and triglycerides are increased in many of the ACR personnel as well [4]. Unless the existing situation is improved, these findings can result in development of cardiovascular diseases and a consequent increase in morbidity in the ACR personnel [5,6]. At present, in obesity therapy there is only a very limited number of drugs in the market that are suitable, effective and safe.

Besides the preparation of orlistat, which decreases the total energy input by blocking intestinal lipase, there is the substance of phentermine available in the Czech Republic. Phentermine is a psychostimulant drug of the phenethylamine class. Phentermine is used for short-term obesity treatment as an appetite suppressant. The drug may increase blood pressure and heart rate. It may also cause palpitations, restlessness, and insomnia. Additionally, phentermine has a potential to cause psychological dependence. On the other hand, phentermine reduces food intake and potentially achieves greater improvements in weight. Although phentermine has some anti-obesity side effects, the substance containing phentermine can still be prescribed in the Czech Republic. According to the statement of the Czech Society for the Study of Obesity declared at the committee meeting on 8 August 2011 there are no reasons not to prolong the registration of the above mentioned drug in the Czech Republic.

Pharmacological treatment of obesity should ensure a long-term sustainable weight loss, possibly positively influence metabolic disorders that cause the development of obesity [7,8]. The aim of the work is to show effectiveness of orlistat and phentermine in outpatient obesity management and to emphasize that pharmacotherapy for obesity is an integral part of the complex therapy of this serious disease.

METHODS

In years 2012 to 2014, a preventive care program with the aim to reduce overweight and obesity in the military personnel was carried out in the ACR. The subjects indicated for an intervention had the Body Mass Index (BMI) value of 28 kg/m^2 and higher. A Military General practitioner in charge who was responsible for the monitored soldiers determined indication for administering pharmacotherapy. He / she also determined which of the two anti-obesity agents is more suitable for the patient in question. As for the mechanism of action, duration of action and side effects, orlistat and phentermine differ from each other. Pharmacological intervention consists of administering a selected anti-obesity agent for three months with the aim to reduce body weight and obesity-related cardiometabolic com-plications in an individual. The administered dose was 120 mg of orlistat three times a day and 15 mg of phentermine once a day. According to the protocol for monitoring the weight loss, each patient under-went an initial physical examination which included determination of the proband´s medical history, physical status, anthropometric and biochemical characteristics. Subsequently, a relevant pharma-cotherapy was instituted. Basic anthropometric parameters such as body weight, BMI, waist cir-cumference and the total amount of adipose tissue were compared in all patients before the adminis-tration of a relevant anti-obesity agent and after a three-month therapy using the same dose of an ef-fective drug. Height was measured using a calibrated measuring device and body weight was weighed using a calibrated stand-on scale. BMI was calculated as BMI = weight / height^2. Waist circumference was measured with a tape measure. The amount of total body fat was measured using Tanita BC-543 analyzer. As for biochemical parameters, selected parameters of saccharide, lipid and protein metab-olisms were monitored. Venous blood samples were obtained on an empty stomach and parameters were determined using laboratory techniques in certified laboratories. Three control examinations followed within three months, each of them after a month. The last control examination was simultaneously a final examination, thus all examinations from the initial one were repeated. Control examinations were carried out to register possible side-effects of administered drugs and subjects' subjective com-plaints. As for subjects, a hypocaloric balanced diet with the energy content of 5.000 up to 6.000 kilojoule (kJ) for females and 6.000 up to 7.000 kJ for males together with the reduction of animal fat intake was recommended. At the same time physical activities and endurance exercises which engage large muscle groups such as walking, cycling, swimming, cross-country skiing etc. for a minimum of 30 minutes and at least three to five times a week were recommended as well.

The obtained data were presented as mean and standard deviation. For statistical analysis of pair data of the first and the last examination, we used pair Student´s t-test with statistical significance at value $p<0.05$.

RESULTS

The total number of soldiers included in the project was 373, but the number of subjects who finished a 3-month pharmacological intervention was 289 (238 males and 51 females). 231 persons out of the mentioned number used orlistat-containing preparations and 58 persons used phentermine-containing preparations. A statistically significant weight loss in both genders, on average by 4.6 ± 4.2 kg in males and by 5.3 ± 4.3 kg in females, was observed in patients taking orlistat within three months. A statistically significant weight loss, on average by 6.5 ± 6.0 kg in males and by 5.2 ± 4.3 kg in females, was also observed in patients taking phentermine for the same period of time. A statistically significant reduction in other anthropometric parameters in both genders (BMI, waist circumference, total amount of body fat) at a statistically significant level ($p<0.001$) was registered as well.

A statistically significant decrease in all monitored anthropometric quantities after a 3-month treatment with anti-obesity agents is shown in Tables 1-2. As for monitored biochemical parameters, a decrease of total cholesterol, HDL cholesterol and glucose at a statistically significant level ($p<0.05$) was observed in the group of females, the same statistically significant decrease, but in triglycerides, was proved in the group of males. Then a decrease of total cholesterol and increase of HDL cholesterol at a statistically significant level ($p<0.001$) was observed in the group of males (Tables 3-4).

DISCUSSION

Good results in the course of treatment with selected anti-obesity agents, that means statistically significant changes especially in anthropometric parameters at the beginning and at the end of the treatment, showed that the rightly indicated pharma-cotherapy has its place in obesity treatment. The stated decrease in weight loss during pharmacotherapy of obesity was in accordance with the recommendation of the Czech Society for the Study of Obesity which declares success of pharmacotherapy in weight loss by a minimum of 0.5 kg a week, or a 5 % reduction of initial body weight [9].

84 persons did not finish the project of a 3-month pharmacological intervention due to their bad cooperation or loss of interest. All subjects received drugs free of charge and some of them did not have any motivation to reduce their weight because there are no penalties concerning this issue in the ACR.

Table 1. Changes of anthropometric parameters after orlistat-containing preparation.

Variables	Males (N = 193) baseline	Males (N = 193) after 3 months	P	Females (N = 38) baseline	Females (N = 38) after 3 months	P
BMI (kg/m²)	33.4 ± 3.3	32.3 ± 5.5	< 0.001	32.7 ± 3.8	30.8 ± 3.7	< 0.001
Body weight (kg)	107.8 ± 13.3	103.3 ± 13.6	< 0.001	92.1 ± 12.4	86.8 ± 12.3	< 0.001
Waist circumference (cm)	110.0 ± 9.5	105.2 ± 10.0	< 0.001	102.1 ± 9.6	94.8 ± 9.1	< 0.001
Body fat (%)	30.2 ± 4.5	28.6 ± 4.6	< 0.001	41.2 ± 5.0	39.4 ± 5.0	< 0.001

Table 2. Changes of anthropometric parameters after fertermin-containing preparation.

Variables	Males (N = 45) baseline	Males (N = 45) after 3 months	P	Females (N = 13) baseline	Females (N = 13) after 3 months	P
BMI (kg/m²)	33.3 ± 3.5	31.4 ± 3.7	< 0.001	30.5 ± 2.4	28.8 ± 2.8	< 0.001
Body weight (kg)	106.1 ± 14.7	99.6 ± 14.8	< 0.001	83.2 ± 9.9	78.0 ± 10.2	< 0.001
Waist circumference (cm)	108.5 ± 9.4	103.6 ± 10.0	< 0.001	89.0 ± 8.6	84.5 ± 8.7	< 0.001
Body fat (%)	31.2 ± 4.5	29.1 ± 3.9	< 0.001	39.4 ± 4.0	38.5 ± 3.9	0.04

Table 3. Changes of biochemical parameters after orlistat-containing preparation.

Variables	Males (N = 193) baseline	after 3 months	P	Females (N = 38) baseline	after 3 months	P
Total cholesterol mmol/l	5.4 ± 1.0	5.2 ±1.0	< 0.001	5.1 ± 0.8	4.9 ± 0.8	0.023
HDL cholesterol mmol/l	1.1 ± 0.3	1.2 ± 0.3	0.256	1.5 ± 0.4	1.4 ± 0.3	0.045
Triglycerides mmol/l	2.2 ± 1.4	2.1 ± 1.3	0.076	1.6 ± 0.7	1.4 ± 0.7	0.058
Glucose mmol/l	5.1 ± 0.9	5.1 ± 0.9	0.181	5.0 ± 0.6	5.1 ± 0.5	0.028
Uric acid µmol/l	375.2 ± 76.5	370.8 ± 74.1	0.217	276.7 ± 69.6	269.6 ± 69.4	0.2

Table 4. Changes of biochemical parameters after fertermin-containing preparation.

Variables	Males (N = 45) baseline	after 3 months	P	Females (N = 13) baseline	after 3 months	P
Total cholesterol mmol/l	5.2 ± 0.8	5.3 ± 1.0	0.048	4.8 ± 1.0	5.0 ± 0.4	0.172
HDL cholesterol mmol/l	1.0 ± 0.3	1.2 ± 0,3	< 0.001	1.5 ± 0.4	1.6 ± 0.4	0.206
Triglycerides mmol/l	1.9 ± 1.1	1.6 ± 0.6	0.003	1.4 ± 1.1	1.0 ± 0.4	0.077
Glucose mmol/l	5.0 ± 0.6	5.0 ± 0.6	0.304	4.9 ± 0.5	4.8 ± 0.4	0.084
Uric acid µmol/l	374.4 ± 81.9	371.0 ± 77.5	0.354	283.5 ± 46.5	375.6 ± 56.2	0.261

Side effects of drugs occurred only in 24 out of 84 subjects who did not finish the project, Most of them suffered from gastrointestinal symptoms due to orlistat use (n=18). But these problems prove that the patient disregarded the dietary recommendations concerning restriction in fat consumption [10,11]. The treatment was stopped in 6 patients treated with phentermine due to side effects such as palpitations, dryness in the mouth, mood swings, nausea [12,13].

The project can be evaluated as successful. A statistically significant decrease in body weight and other anthropometric parameters at a statistically significant level ($p<0.001$) was achieved in indicated individuals during a 3-month substitution by selected anti-obesity agents. Statistically significant changes just in some biochemical parameters at a statistically significant level ($p<0.05$) can be explained by a relatively short period of pharmacotherapy.

In a group of females who were treated with a phentermine-containing preparation no statistically significant changes were observed, probably due to a small group. Thus, pharmacotherapy of obesity proved its competence in a complex of therapeutic measures against this metabolic disease. Both selected anti-obesity agents accomplished their purpose and indication. At a given moment they were the best and only possible choice. According to clinical studies, only orlistat 120 mg can efficiently reduce absorption of fat in the duodenum [14,15,16]. The indication of phentermine-containing preparation from an experienced physician can efficiently reduce a patient´s weight as well [12,17].

Based on positive results of the preventive care program in the ACR, it is possible to enlarge the preventive and pharmacological intervention to other elements of the metabolic syndrome, or to other risk factors of cardiovascular diseases. All non-communicable diseases belong to the main causes of morbidity in the Czech population and by decreasing them we can reach a higher percentage of healthy and deployable soldiers. The right application of relevant intervention measures gives a high probability of de-creasing overweight and obesity prevalence in the ACR and simultaneously, decreasing morbidity in the ACR personnel.

Only a complex approach to obese patients using all available therapeutic methods has a chance of success. Anti-obesity drug administration without other regimen measures is much less effective. Weight loss has a positive influence on the quality of life and can significantly decrease health risks of all the obese patients [18,19]. Orlistat or phentermine treatment is not financially demanding for the health care system because this treatment is paid by the patients themselves.

The current affordability of both the preparations in the Czech market enables a great number of obese patients to take these medications.

CONCLUSION

We can state that in indicated patients we have proven a positive effect of orlistat or phentermine substitution on their weight loss. An anti-obesity agent containing orlistat is a modern drug for a long-term, safe and effective weight loss provided the basic diet and exercise regimen are followed. An anti-obesity agent containing phentermine can be also considered a useful drug provided the indication criteria are maintained. A disadvantage of phentermine is that a long-term therapy is impossible. Besides dietary recommendations, behavioural techniques and increased regular physical activity, pharmacotherapy of obesity is an integral part of the complex therapy of this disease [20,21].

CONFLICT OF INTEREST

Authors state no conflict of interest

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