TREATMENT OF OBESITY DISEASE MODERN OBJECTIVES.

Sulaymanova Nilufar Ergashevna.
Munisa Ablakulova Xamrakulovna
Nodira Egamberdievna Yuldashova
Makhmudov Sardor Mamasharifovich
Samarkand State Medical University

Abstract: *There are many angles to consider in drug treatment of obese patients. On the one hand, some specific weight loss drugs are available, on the other, several drugs are associated with unintentional weight changes. When treating an obese patient for any given disease, several physiological changes may influence the pharmacokinetic properties of the drugs required. Thus, increased body weight may influence the efficacy and safety of some drug treatments.*

Keywords: *high-calorie food, physical activity, eating excessive amounts.*

Obesity is generally caused by consuming more calories – particularly those in fatty and sugary foods – than you burn off through physical activity. The excess energy is stored by the body as fat. Obesity is an increasingly common problem because for many people modern living involves eating excessive amounts of cheap, high-calorie food and spending a lot of time sitting down, at desks, on sofas or in cars.

Even more complicated is the situation after weight reduction surgery. Due to the various changes to the gastrointestinal tract induced by the different surgical techniques used, and the dynamic changes in body composition thereafter, drug dosing has to be constantly reconsidered. Whereas all of these issues are of clinical importance, none of them have been investigated in the necessary depth and broadness to ensure safe and efficacious drug treatment of the massively obese patient. Individual considerations have to be based on comorbidities, concomitant medication, and on specific drug properties, for example, lipophilicity, volume of distribution, and metabolism. In this article we summarize the data available on different aspects of drug treatment in the obese patient with the hope of improving patient care.

More than 1.9 billion adults worldwide are overweight, including over 650 million with clinically relevant obesity, and the number of obese patients continues to rise. Most likely, this development will not change substantially in the foreseeable future due to the absence or failure of preventive measures. Obesity is associated with increased mortality and comorbidity, due, in part, to specific obesity-associated diseases such as type 2 diabetes mellitus, hypertension, cardiovascular diseases, respiratory dysfunction, some carcinomas, nonalcoholic fatty liver disease, and orthopedic degenerative diseases. But clinical management of obese patients is often complicated whether the disease is obesity-associated or not. Specific guidelines for weight-adjusted dose

modifications are lacking for almost all drugs available, although there is considerable concern that some drugs, especially those with a narrow therapeutic range, might require dose adjustment in obese patients. There is also only scant evidence on the effectiveness of drugs used regularly in obese patients. One reason for the lack of data is underrepresentation of patients with obesity in clinical trials. In summary, physicians should be aware of how current pharmacotherapy influences metabolism and body weight, and how pharmacotherapy is influenced by obesity.

Several drugs have been developed specifically to reduce body weight; some of these have gained marketing authorization during the last 5 years, whereas several others are still in development. Besides that, weight loss is an important side effect of some commonly used drugs. Well-known examples include Topiramate, an antiepileptic drug that is also used for migraine prophylaxis, Roflumilast in chronic obstructive pulmonary disease (COPD) therapy, and Bupropion and Fluoxetine in the treatment of depression. For some other drugs, the weight-reducing effect is not the primary treatment indication, but is desirable, and probably explains part of the effectiveness. Important examples are sodium-glucose transport protein 2 (SGLT2) inhibitors and glucagon-like peptide-1 receptor (GLP1) agonists when used to treat type 2 diabetes mellitus. In some diseases where several drugs are available, a specific drug may be chosen because of its known weight-lowering side effect, for example, Topiramate seems to be a good treatment option for obese patients with migraine. But weight-reducing effects may also lead to off-label use of some drugs, and abusive use of some of these drugs cannot be ruled out, for example, Methylphenidate.

Of course, not every obese patient needs pharmacological treatment for weight loss. Exercise, diet, and behavior modification should always be the cornerstones of anti-obesity treatment. However, many affected patients do not lose weight, or fail to maintain weight loss, with that approach. There is consensus that anti-obesity drug treatment may be considered for individuals who fail to respond to lifestyle interventions after 6 months of treatment, and have a body mass index (BMI) of >30 kg/m2 or a BMI of >27 kg/m2 with weight-associated comorbidities. However, weight reduction per se should not be the main goal of treatment. Improvement of obesity-associated comorbidities like hyperglycemia, hyperlipidemia, and hypertension are at least of equal importance. However, expectations in regard to weight loss efficacy are often very unrealistic. Patients and healthcare providers should realize that efficacy of available anti-obesity drugs is often limited to a reduction of 5–10% of body weight over a 1-year period. Drug-induced weight loss typically does not occur for more than 6–8 months. Obesity is a chronic disease and requires long-term treatment. Many patients and health care providers still do not act according to this concept. No one would suggest discontinuing antidiabetic medication when hemoglobin A1c (HbA1c) is improved after a new medication was started. Regarding obesity, there is regular dispute about regained weight after anti-obesity medication was discontinued, which

demonstrates the need for effective weight maintenance strategies. As with other chronic diseases, anti-obesity medication should be viewed as a next-step treatment option on basis of a continuous healthy lifestyle regime including increased daily activity and a calorie-deficit diet. Drug therapy should never be a standalone therapy, or even universal remedy, against obesity. Pharmacotherapy can be considered as an adjunct to bariatric surgery to maintain weight and prevent weight regain some time after surgery. In some cases, added drug treatment can even facilitate further weight loss in these patients.

Anti-obesity drugs in Europe.

There is a wide range of Anti-obesity drugs in Europe, from amphetamine-type medicines to preparations made from algae and homeopathic medicines. However, only a few of these drugs are recommended in current guidelines. Anti-obesity drugs have been used for more than 100 years. Some of the drugs still available activate the sympathetic nervous system similar to the action of amphetamines. These amphetamine-type drugs can cause cardiovascular and psychological adverse effects. Moreover, the product information summary contains warnings regarding pulmonary arterial hypertension and addiction potential when taken over a long period of time. These drugs may be effective in some patients, but are authorized only for short-term use (4–12 weeks), which does not fit into a well-structured and long-term effective obesity therapy. Moreover, type 2 diabetes mellitus is a contraindication for sympathomimetic drugs, and, therefore, many patients who seek weight reduction therapy are not suitable for this kind of treatment. Another factor is the lack of safety data from large randomized controlled trials. One exception may be Cathin (=Norpseudoephedrine), because at least a small randomized controlled trial was conducted recently. Some of the available anti-obesity preparations contain relevant amounts of ethanol or iodine, which can be a risk in patients with alcohol dependency or thyroid gland diseases. Swelling agents from algae or crustacean-derived chitin products to bind dietary lipids may reduce absorption of other drugs like oral contraceptives or thyroid hormones. Thus, prescription or recommendation of these drugs and preparations requires a considerable knowledge about their properties and constituents.

With Orlistat, an average weight reduction of about 3.8 kg above placebo was seen in clinical trials. In patients with type 2 diabetes mellitus, weight reduction was about 2.5 kg. The observed weight reduction was associated with a reduction in blood pressure; however, cardiovascular endpoint studies with orlistat are still lacking. The incidence of type 2 diabetes mellitus is lowered in obese patients with impaired glucose tolerance when treated with orlistat compared with lifestyle interventions alone. Orlistat is a lipase inhibitor, reducing dietary fat uptake in the small intestine by about 30%. Thus, efficacy and side effects depend on daily fat intake. Intestinal side effects (fatty/oily stool, fecal urgency, oily spotting, increased defecation, fecal incontinence, flatus with discharge, and oily evacuation) are common problems with Orlistat. Concomitant use of

natural fibers (psyllium mucilloid) might help to ameliorate these adverse gastrointestinal effects. Orlistat does not affect cytochrome P450 metabolism, but drug interactions are possible due to resorption inhibition in the small intestine. For example, this interaction is well documented for concomitant medication with ciclosporin. Resorption of fat-soluble vitamins might also be reduced, and oral multivitamin supplementation should be considered during treatment. Currently, Orlistat is the only marketed anti-obesity drug of this category (lipase inhibitor) in Europe. Cetilistat (ATL-962) is equipotent to Orlistat regarding fecal fat excretion, but seems to have a somewhat better gastrointestinal side effect profile. Cetilistat has gained marketing authorization in Japan, and an approval in the US is expected.

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