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Novel findings regarding treatment obesity and weight-related comorbidities – the systemic literature review

URBAŃSKA Karina, POPIELA Dariusz, STOJAK Łukasz, KWIATKOWSKI Filip, GREGO Katarzyna, GREGO Mateusz, BACZEWSKI Mateusz, CZYŻ Witold

lek. Karina Urbańska, Central Teaching Hospital of the Medical University of Lodz located at ul. Pomorska 251, 92-213 Lodz, Poland
e-mail: karina.urbanska2@gmail.com
ORCID: https://orcid.org/0000-0002-1981-9281

lek. Dariusz Popiela, Military Institute of Aviation Medicine, Krasińskiego 54/56 Street, 01-755 Warsaw, Poland,
e-mail: dariusz.popiela1@gmail.com
ORCID: https://orcid.org/0009-0009-8648-2365

lek. Łukasz Stojak, 10th military clinical hospital with polyclinic ul. Powstańców Warszawy 5, 85-681 Bydgoszcz, Department of Normal Anatomy, Collegium Medicum in Bydgoszcz, Nicolaus Copernicus University in Torun, ul. Łukasiewicza 1, 85-821 Bydgoszcz, Poland
e-mail: luk.stojak@gmail.com
ORCID: https://orcid.org/0009-0008-9910-0445

lek. Filip Kwiatkowski, Military Institute of Aviation Medicine, Krasińskiego 54/56 Street, 01-755 Warsaw, Poland
e-mail: filip.karol.kwiatkowski@gmail.com
ORCID: https://orcid.org/0009-0006-3873-1265

lek. Mateusz Grego, 10th Military Clinical Hospital with Polyclinic ul. Powstańców Warszawy 5, 85-681 Bydgoszcz, Poland
e-mail: mateuszgrego@onet.eu
ORCID: https://orcid.org/0009-0008-4079-2168

lek. Katarzyna Grego, 10th Military Clinical Hospital with Polyclinic ul. Powstańców Warszawy 5, 85-681 Bydgoszcz, Poland
e-mail: k.grego521@gmail.com
ORCID: https://orcid.org/0009-0005-7388-8885

lek. Mateusz Baczewski, 10th military clinical hospital with polyclinic ul. Powstańców Warszawy 5, 85-681 Bydgoszcz, Poland
e-mail: mateuszxbaczewski@gmail.com
ORCID: https://orcid.org/0009-0007-2857-5219

dr n. med. Witold Czyż, Central Teaching Hospital of the Medical University of Lodz located at ul. Pomorska 251, 92-213 Lodz, Poland
e-mail: witoldczyz@googlemail.com
ORCID: https://orcid.org/0009-0006-4442-9900

ABSTRACT

Obesity and overweight are a growing health problem worldwide and are recognized as risk factors for many health complications and increased mortality. Therefore, it is necessary to take decisive action to fight the obesity epidemic to avoid significant costs associated with the treatment of diseases related to excess body weight. Recent years have brought many new drugs that are very effective in obesity treatment and even more are in clinical trials. This review aims to synthesize the literature regarding new drugs and their effectiveness in treating obesity and their impact on related diseases. A systematic search was conducted across

multiple sources, including PubMed, Google Scholar, ResearchGate, ClinicalTrials, FDA, and EMA databases. Currently, the most effective medications seem to be tirzepatide and retatrutide, which might provide more than 15% weight loss. However, other drugs show promising results in improving glycemic control, cardiovascular health (semaglutide and tirzepatide), lipid levels, the regression of fibrosis (survodutide), or alleviating OBS symptoms (tirzepatide). Tailored therapy combining both medication's weight-reducing capacity and the patient's comorbidities provides the most beneficial effects.

Keywords: obesity, overweight, obesity treatment, tirzepatide, retatrutide, semaglutide, CagriSema, survodutide, orfogliprone, GLP-1 agonist, obesity-related complications

INTRODUCTION

Obesity is recognized as a chronic disease and is frequently referred to as the epidemic of the 21st century. The World Health Organization (WHO) defines obesity as having a body mass index (BMI) over 30 kg/m² and overweight as BMI greater than 25 kg/m². (1) The World Obesity Atlas 2023 reports that 38% of the world's population is either overweight or obese, with a projected further increase by 2035. (2) According to data from Eurostat in 2019, 53% of the European population has a BMI of more than 25. (3)

Excess body weight leads to a high risk of mortality and various disorders such as cardiovascular diseases, type 2 diabetes mellitus, atrial fibrillation, dyslipidemia, asthma, chronic obstructive pulmonary disease, obstructive sleep apnea, hypertension, cardiovascular incidents, esophageal reflux disease, gallbladder lithiasis, metabolic-dysfunction associated steatotic liver disease (previously known as non-alcoholic fatty liver disease), polycystic ovary syndrome, hypogonadism, infertility, osteoarthritis, stress urinary incontinence. (4–8) The link between obesity and cancer risk has been documented, indicating at least thirteen different types of cancers, especially those of the digestive tract, such as colon, esophageal, pancreatic, and liver cancers. The literature also mentions endometrial, kidney, ovarian, and thyroid cancers. Colon cancer is most frequently diagnosed in obese men, and breast cancer in obese women. (9) Weight gain also leads to the development of insufficient sleep and

insomnia and increases the risk of depression and anxiety. (10, 11) In general, BMI > 25kg/m² correlates with a shorter life expectancy, and in patients with BMI > 40kg/m², the risk of death due to obesity increases to 100%. (9)

Obesity has become the second leading cause of preventable death, following smoking, generating global healthcare spending of approximately $700 billion annually. Due to the growing burden of disease and healthcare costs, it is crucial to incorporate innovative solutions. Achieving a weight loss (WL) of 5-10% can lower the risk of comorbidities and significantly improve health and quality of life. (12) Nowadays, drugs that effectively reduce body weight are gaining importance. Anti-obesity medications are recommended for individuals with a BMI > 30kg/m² or a BMI > 27kg/m² with weight-related comorbidities by The U.S. National Institute of Health (NIH). (13) The Food and Drug Administration (FDA) has approved six drugs: orlistat, phentermine-topiramate, naltrexone-bupropion, liraglutide, semaglutide, and since November 2023 also tirzepatide — all for long-term use. On the other hand, the European Medicines Agency (EMA) has approved five of them - without phentermine/topiramate. (12–14)

In this review, we analyzed scientific studies on anty-obesity medications, describing their effectiveness in treating complications related to excess body weight. We discussed the most promising medicaments in the obese market.

MATERIALS AND METHODS:

The paper was based on literature gathered from various databases, including PubMed, Google Scholar, ResearchGate, ClinicalTrials, FDA and EMA. A manual snowball search was also conducted to select references from twin studies and reviews. Only English-language articles met the inclusion criteria for the analysis. The study refers to the latest drugs not only approved by the FDA or EMA, but also those during clinical trials. The collected data were analyzed for the treatment of obesity-related complications, obesity and overweight.

Tirzepatide

Tirzepatide is a GLP-1/GIP receptors co-agonist administered subcutaneously once a week. During the double-blind, placebo-controlled trial SURMOUNT-3 tirzepatide induced a mean WL of 18,4% after 72 weeks of therapy, compared to a 2.5% increase in body weight observed in the placebo group.

The SURPASS 1-6 trials evaluated the effectiveness of tirzepatide in patients with diabetes and obesity, comparing it with other antidiabetic drugs or placebo. The SURPASS-1 clinical trial focused on the effectiveness of tirzepatide versus placebo in patients with obesity and type 2 diabetes. After 40 weeks of treatment, results showed significant superiority of tirzepatide over placebo in controlling glycated hemoglobin (HbA1c). In the tirzepatide group, 92% of participants achieved HbA1c below 7.0%, while in the placebo group only 19% reached this level. Furthermore, tirzepatide normalized HbA1c to below 5.7% in 52% of patients, compared to 1% in the control group. The ongoing study SURPASS-CVOT is currently examining changes in HbA1c levels, as well as number of myocardial infarctions, strokes, and cardiovascular deaths. (15) Another study, named SUMMIT was a double-blind, randomized, placebo-controlled trial that included 731 patients with heart failure with preserved ejection fraction (HFpEF), and BMI ≥30kg/m². Over 52 weeks, one group of the participants received tirzepatide (administered subcutaneously at a dose of up to 15 mg once a week), while the other received a placebo. The results showed that cardiovascular death or worsening of heart failure occurred less frequently in the tirzepatide group (9.9%) compared to the placebo group (15.3%). In addition, tirzepatide revealed a positive effect on the patients' physical capacity. By the end of the study, participants receiving the drug increased their 6-minute walk distance by an average of 26.0 m, whereas the placebo group increased their 6-minute walk distance score only by 10.1 m. (16) The SYNERGY-NASH study was also conducted to assess the safety and efficacy of tirzepatide in patients with metabolic dysfunction–associated steatohepatitis (MASH) and moderate to severe liver fibrosis. Participants were randomly assigned to 4 groups: three of them received tirzepatide with doses of 5 mg, 10 mg, and 15 mg once a week subcutaneously, and one group received placebo. Laboratory parameters, imaging (including elastography and MRI) and liver biopsy were assessed. After 52 weeks, MASH (without worsening of fibrosis) was observed to resolve by 62% at the 15 mg dose, compared to 10% in the placebo control group. Additionally, in all tirzepatide groups, a reduction in fibrosis of about 50% was observed regardless of dose, with a 30% reduction in patients taking placebo. (17) The results of the

SURMOND-OSA study were already published. Two parallel studies were conducted over 52 weeks to evaluate the efficacy of tirzepatide in treating obstructive sleep apnea (OSA) in individuals with obesity. The first study involved patients not using Continuous Positive Airway Pressure (CPAP), while the second included patients under the CPAP treatment. In both cases, a comparable reduction in the Apnea-Hypopnea Index was noted, with a slight advantage in patients using CPAP. Participants experienced a reduction of 25.3 and 29.3 events per hour thanks to tirzepatide compared to 5.3 and 5.5 events per hour for the placebo groups. The research indicates that tirzepatide provides a relevant improvement in obesity-related obstructive sleep apnea by addressing the underlying etiology. (18)

Clinical trials are currently underway to assess the therapeutic efficacy of tirzepatide in treating other metabolic complications. The SURMOUNT-MMO study examines the drug's effect on reducing morbidity and mortality in patients with obesity, while the TREASURE-CKD study assesses its efficacy in treating chronic kidney disease in obese patients. (15)

A recent study also assesses the potential of tirzepatide for treating endometrial cancer. These open up potentially revolutionary therapeutic perspectives, although they are currently in the early stages of experiments in mouse models. The study evaluated the effect of tirzepatide on tumor growth and body weight in a mouse model of obesity-induced endometrial cancer. The drug significantly reduced tumor weight by 66.4% in obese mice and 60.1% in lean mice, and also caused a significant reduction in body weight by 20.1% in obese and 16.8% in lean mice after 4 weeks of treatment. The analysis indicated that medication affects different metabolic and signaling pathways in endometrial cancer tumors from obese and lean mice. Therefore, the research may be important for further studies on tirzepatide as a potential additional drug for the treatment of endometrial cancer especially in obese patients. (19)

Retatrutide

Retatrutide is a triagonist of the GIP, GLP-1 and glucagon receptors. The results of a randomized Phase 2 study evaluating the efficacy and safety of retatrutide have been published. After 48 weeks of treatment at a dose of 12 mg, the mean percentage reduction in body weight was 24.2%, compared to 2.1% in the placebo group. In women, a mean WL of 28.5% was observed. This is the greatest WL reported in clinical trials. In the group receiving 12 mg of retatrutide, 100% of participants achieved ≥5% reduction, 93% achieved ≥10%

reduction, and 83% achieved ≥15% reduction of body weight. The drug also improved other cardiometabolic parameters, including blood pressure, HbA1c, fasting glucose, insulin sensitivity, and lipids levels. 72% of participants with prediabetes at baseline returned to normoglycemia after 48 weeks of retatrutide treatment. 41% of participants in the 8 mg retatrutide group and 30% in the 12 mg group were able to discontinue at least one of the antihypertensive medications during the 48-week treatment period, thanks to reduced blood pressure. The triple agonist also has shown beneficial effects in the treatment of metabolic-dysfunction associated steatotic liver disease. After 48 weeks, it led to remission of fatty liver disease in >85% of participants. (20) A phase 3 clinical trial, known by the acronym TRIUMPH (Trial of Retatrutide in Uncontrolled Metabolic and Physiological Health), is currently underway to assess the safety and efficacy of retatrutide. The investigation includes obese participants with at least one weight-related comorbidity, such as OBS, type 2 diabetes mellitus, cardiovascular disease, and arthritis. (5) Retatrutide seems to be a very promising drug in the fight against obesity. The results of studies on the control of comorbidities may have important implications for future strategies for the treatment of obesity.

Semaglutide

Semaglitide is a glucagon-like peptide-1 receptor agonist. It stimulates insulin release and inhibits glucagon secretion, leading to better glycemic control. (21) The STEP 5 phase 3 study evaluated the efficacy and safety of semaglutide at a dosage of 2.4 mg administered once weekly subcutaneously over 104 weeks in overweight or obese adults. The results indicated that patients using the medication achieved a mean weight decrease of 15.2% versus 2.6% for those receiving a placebo. Clinically significant changes in cardiometabolic parameters were also noted. Specifically, 77.1% of patients on semaglutide achieved a WL of at least 5%, vs 34.4% of those in placebo group. Additionally, systolic blood pressure decreased by an average of 5.7 mmHg in the semaglutide group, compared to 1.6 mmHg for placebo. In addition, the medication showed a positive effect on lipid metabolism, leading to a reduction in LDL cholesterol by 3.4% (placebo - 2.7%), VLDL cholesterol by 21.5% (placebo 3.3%), triglycerides by 21.9% (placebo -3.7%). Semaglutide also improved HbA1c by 0.3%, compared to 0.1% for placebo. (22) The effect of semaglutide on the circulatory system was

assessed in the phase 3 clinical trial SELECT. The study was conducted across 41 countries, involved 17,604 adults with BMI ≥27 kg/m² and diagnosed with cardiovascular disease, without diabetes. In participants administered 2.4 mg of semaglutide subcutaneously weekly, the 3-year study revealed a reduction in major adverse cardiovascular events (MACE) by 20% compared to placebo. MACE was defined as a composite endpoint of cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke. The benefits of semaglutide treatment were noticed in patients with heart failure with reduced ejection fraction (HFrEF) and with HFpEF. (23) Ongoing phase 3 studies are exploring the effects of semaglutide in obese patients with heart failure (STEP-HFpEF), with type 2 diabetes (STEP HFpEF DM) or with knee osteoarthritis. (24) Currently, a higher dose of semaglutide (7.2 mg once weekly), administered subcutaneously is evaluated in a phase 3 trial. (5)

CagriSema

CagriSema combines the mechanism of two peptides: cagrilintide, a long-acting amylin analogue and semaglutide, a GLP-1 receptor agonist. Amylin is a hormone released by the pancreas together with insulin after a meal. It acts in central nervous system by signaling a feeling of satiety and peripherally by inhibiting gastric emptying. It also reduces glucagon release after meals, contributing to better glycemic control. (25)

In the study conducted by Enebo et al. (2021), phase 1b trial, the group taking cagrilintide (1.2-2.4 mg) plus semaglutide (2.4 mg) lost 17.1% of their body weight after 20 weeks, compared with 9.8% in the semaglutide control group. The study included patients who were obese or overweight but did not have diabetes. (26,27) The combination of these two substances also shows higher effectiveness in reducing body weight (−15.6%) in comparison with cagrilintide –(8.1%) and semaglutide (−5.1%). In contrast to the trial above, another study by Frias J P et al. investigated CagriSema use in overweight and obese patients with type 2 diabetes mellitus. The results revealed that CagriSema reduced HbA1c level by 2.2%, compared with cagrilintide (0.9%), but did not show a meaningful difference compared to semaglutide (1.8%). The medication also influenced the reduction of fasting blood glucose levels. The combination of these two substances also shows higher efficacy in reducing body weight (−15.6%) in comparison with cagrilintide –(8.1%) and semaglutide (−5.1%). (27)

Currently, there are significant clinical trials underway to investigate CagriSema and its potential to improve obesity-related comorbidities. REDEFINE 3 (NCT05669755), is a randomized phase 3 clinical trial designed to evaluate the effects of CagriSema 2.4 mg/2.4 mg on cardiovascular events in 7,000 participants. Another trial (NCT05567796), which began in 2022, is a randomized study comparing the effects of the CagriSema, cagrilintide, semaglutide, and placebo on kidney damage in over 600 people with chronic kidney disease, type 2 diabetes, and excess body weight. Both studies are expected to provide valuable information on the safety and efficacy of CagriSema in relation to cardiovascular and nephrological diseases. (25,27)

Survodutide

Survodutide is a dual agonist of the Glucagon-Like Peptide-1 (GLP-1) receptor and the glucagon (GCG) receptors. It lowers blood glucose levels through GLP-1 receptor activation and increases energy expenditure and lipolysis via GCG receptor activation. (28)

After 46 weeks of phase 2 clinical trial, patients who received 0.6-4.8 mg of survodutide once a week experienced an average weight reduction of 6.2% to 14.9%, depending on the dose, while the placebo group only achieved a WL of 2%. The drug progressed to the phase 3 of this study. (5,29) Another phase 2 placebo-controlled clinical trial was conducted to assess the efficacy of survodutide in the treatment of MASH and fibrosis. A total of 293 participants were divided into four groups: those taking survodutide at a dose of 2.4 mg, 4.8 mg, 6.0 mg, and placebo. Interestingly, the study indicated that the dual agonist was most effective at a dose of 4.8 mg rather than the highest dose. At this dosage, 68% of participants experienced notable improvement in MASH without worsening of fibrosis, compared to only 14% of participants in the placebo group. Additionally, 67% of those receiving the 4.8 mg dose showed a reduction of liver fat by at least 30%, whereas this effect was observed in just 14% of the placebo group participants. Furthermore, in the group with the most effective dose, 36% of patients demonstrated regression in fibrosis by at least one grade. Overall, the study confirmed the effectiveness of survodutide in the treatment of MASH, reducing both fibrosis and liver steatosis. (30) In studies evaluating the effectiveness of survodutide in improving glycemic parameters, the drug reduced HbA1c levels, demonstrating a dose-response relationship. The greatest reduction of 1.71% achieved the group receiving 1.8 mg weekly, compared to a change of just 0.2% in the placebo group. (28)

The SYNCHRONIZE-CVOT Phase 3 clinical trial is currently ongoing to evaluate the safety and efficacy of survodutide in the treatment of obesity and its cardiovascular complications. The trial includes patients with a BMI ≥27 kg/m² and either established cardiovascular disease, chronic kidney disease or at least two weight-related complications or cardiovascular risk factors. (4)

Orfogliprone

Orforgliprone is a GLP-1 agonist administered orally once daily. As a small molecule, it does not need to be taken on an empty stomach, making it more convenient for users. (25) The double-blind, phase 2 study involved adult patients with obesity or overweight and at least one weight-related disorder, without diabetes. Participants were divided into 5 groups: each receiving different doses of orforgliprone (12 mg, 24 mg, 36 mg or 45 mg once daily) or a placebo. After 36 weeks, the reduction in body weight was up to 9.4-14.7% in the groups taking orforgliprone, compared to 2.3% in the placebo group. Furthermore, 46-75% of participants taking orforgliprone achieved at least a 10% reduction in body weight, compared to 9% in the placebo group. There was also a notable reduction in systolic blood pressure, with a decrease of 10.5 mmHg observed at 26 and 36 weeks for those taking the drug, compared to reductions of 3.6 mmHg and 1.8 mmHg in those not taking the drug. (31) Additionally, the ATTAIN-1 phase 3 study is currently underway to evaluate the safety and efficacy of orforgliprone in the treatment of obesity. The research is going to enroll 3,000 participants with a BMI ≥27 kg/m² and at least one of the following treated or untreated weight-related comorbidities: hypertension, dyslipidemia, obstructive sleep apnea, and cardiovascular disease. The trial is expected to last 72 weeks and an additional 4-week follow-up period. (32) Another ongoing phase 3 study is ATTAIN-2, which aims to include overweight or obese patients diagnosed with type 2 diabetes, having an HbA1c level between ≥7% to ≤10%. The results of this study will be assessed after 77 weeks. (33)

CONCLUSIONS

Obesity is a widespread issue that has a destructive effect on the quality of life and is a recognized risk factor for serious diseases. This review presents new data on the effectiveness

of anti-obesity drugs and their role in treating obesity-related complications. Survodutide has been highlighted for its ability to reduce liver steatosis in patients with MASH. Individuals with cardiovascular burden see substantial benefits from taking semaglutide or tirzepatide, by reducing the number of cardiovascular events. Ongoing studies are also evaluating the effects of tirzepatide, CagriSema, and retatrutide on the circulatory system. Tirzepatide, apart from being highly effective in reducing body weight, has also proven to be an useful drug in the fight against OSA. The diverse range of pharmacological agents allows for tailored therapy that considers the patient's profile and existing comorbidities. Reviewed trails focus mainly on the effectiveness of anti-obesity medications in addressing complications related to obesity, such as type 2 diabetes, cardiovascular events, heart failure, MASH, and chronic kidney disease. Only few studies include obstructive sleep apnea, osteoarthritis pain, gynecologic benefits or cancerogenesis. Taking into account that many anti-obesity drugs are currently undergoing clinical trials with even more during an early stage of development, we need to analyze their impact on obesity-related disorders to create much more specific guidelines for patients. Therefore, the impact of obesity treatment on alleviating other comorbidities requires further investigation.

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