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Obesity Treatment

A Focus on Pharmacotherapy of Weight Management

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Obesity, a chronic multifactorial disease, has been on the rise in the United States in recent years. It paves a way to other chronic conditions and related morbidity and mortality. The treatment of obesity should have a chronic approach involving lifestyle modifications from the very beginning. Along with reduced calorie diet, increased physical activity, and behavior modifications, various short- and long-term pharmacological agents are available to help with the weight loss. For qualifying patients, selection of an appropriate agent based on its mechanism, efficacy, and safety profile as well as patient preference can provide desired outcomes. This medical weight management should be a multidisciplinary approach involving nurses to provide continuous patient education and motivation.

Introduction

Obesity is a multifactorial, chronic, progressive disease associated with a surplus of body fat (Yanovski & Yanovski, 2014). By definition, for most individuals, obesity is defined as a body mass index (BMI) of 30 or greater and is further classified into subcategories based on BMI ranges as listed in Table 1 (Centers for Disease Control and Prevention [CDC], 2019). Per the National Center for Health Statistics (NCHS) data brief, obesity affected 93.3 million adult Americans in 2015–2016 (Hales, Carroll, Fryar, & Ogden, 2017). This serious condition if left untreated can cause several coexisting chronic diseases such as hypertension, dyslipidemia, atherosclerotic cardiovascular disease, sleep apnea, osteoarthritis, diabetes, and certain cancers that can further lead to death (Obesity Expert Panel, 2013).

Specific to osteoarthritis, obesity has been shown to increase the risk of osteoarthritis of the knees and hips and subsequent need for total knee and hip arthroplasty (Bourne, Mukhi, Zhu, Keresteci, & Marin, 2007). Proposed theories that explain the function of obesity in the development of osteoarthritis include higher biomechanical loading on joints, high fat mass replacing the lean body mass, chronic systemic inflammation, and metabolic syndrome. For patients undergoing knee and hip procedures, obesity further increases the risk of thromboembolic events (Mihalko, Bergin, Kelly, & Canale, 2014). In addition to considering these concomitant health complications, the overall medical cost for obesity-related services should be of concern. An estimated cost for inpatient, non-inpatient, and prescription drug for obesity management in the United States was $147 billion in 2008 (Finkelstein, Trogdon, Cohen, & Dietz, 2009). It therefore becomes important to provide multidisciplinary management of obesity.

Various modalities for obesity management exist including behavioral modification and physical activity, community-based programs, commercial weight loss, medical weight management, and bariatric surgery (Jensen et al., 2014). The medical weight management is conducted combining lifestyle modifications and Food and Drug Administration (FDA) approved medications for weight loss. A total of six different pharmacological agents are approved by the FDA for weight loss, the most recent one being approved in 2014. This article focuses on these approved pharmacotherapeutic agents, including their pharmacology, place in therapy, patient education, efficacy, and safety concerns.

Pathophysiology of Obesity

Understanding the underlying pathophysiology is imperative to understand how these drugs assist in weight management. The cause of obesity is complex and multifactorial that includes behavioral factors, environmental factors, genetic abnormalities, and various health conditions as well as certain medications (CDC, 2019). Behavioral and environmental factors that can contribute to obesity include personal lifestyle choices such as diet and physical activity routines, as well as poor access to healthy food or means of performing physical activity. Genetic abnormalities, known as monogenic obesity,

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Table 1. Obesity Classification Based on Body Mass Index

Body Mass Index Range	Obesity Classification
30 to <35	Class I
35 to <40	Class II
≥40	Class III

themselves do not play a big role as much as they do in a combination with behavioral and environmental factors (CDC, 2013). All in all, about 50 different genes have been implicated in obesity cause; however, most alone have a relatively minute clinical effect that would result into clinically significant weight gain.

Physiologically, appetite is controlled by the brain when it receives incoming signals from adipose tissues and the gut (Flier & Maratos-Flier, 2018). These signals are impacted by various hormones such as leptin, insulin, and cortisol and various gut peptides such as ghrelin. These further regulate expressions of various peptides in the brain that impact serotonergic, catecholaminergic, and opioid-signaling pathways. The brain incorporates all these signals and synthesizes a response for consuming food and expending energy; if there is dysregulation in any of these signals, however, it can lead to increased consumption of food and decreased energy expenditure. The available pharmacological agents work on these signals and pathways in order to reduce food consumption and increase energy expenditure.

Treatment Approach

The first step of medical weight management is lifestyle modifications (Apovian et al., 2015; Jensen et al., 2014; Obesity Expert Panel, 2013). It comprises nonpharmacological interventions including healthy diet, increasing physical activity, and behavioral modifications. Prepackaged meal replacement programs are available under the medical provider's supervision to help restrict caloric intake while making behavioral changes. The goal is to have patients slowly adopt self-prepared meals and maintain that healthy lifestyle on an ongoing basis. These nonpharmacological modalities form a backbone to all the obesity treatments and therefore should be highly emphasized even after the weight management medications are added (Apovian et al., 2015; Jensen et al., 2014). Medications are generally added if lifestyle modifications alone do not provide desirable weight loss. Addition of pharmacotherapy to lifestyle modifications is recommended for patients with BMI of 30 or more or BMI of 27 or more with two or more comorbidities (Apovian et al., 2015; Jensen et al., 2014). These comorbidities include hypertension, diabetes, prediabetes, and dyslipidemia, among others.

Available Pharmacotherapeutic Agents

As summarized in Table 2, six different medications are now FDA approved for medical weight management as an adjunct to lifestyle modifications including reduced calorie diet and increased physical activity. All of them, with the exception of orlistat, work on appetite suppression by promoting satiety, increasing energy expenditure, or both (Apovian et al., 2015). These agents are further categorized by their approved length of use: short-term, generally 12 weeks or less, and long-term or chronic use. The short-term agents include phentermine, whereas the long-term agents include orlistat, lorcaserin, phentermine-topiramate, naltrexone-bupropion, and high-dose liraglutide. It should be noted that although there are specific contraindications for use with each of these drugs, pregnancy remains the common contraindication of all.

Phentermine (Adipex-P, Lomaira)

Phentermine is FDA approved for short-term monotherapy for weight management, given limited data from clinical trials on chronic use and cardiovascular safety (Apovian et al., 2015). It promotes release of norepinephrine that results in increased energy expenditure and appetite suppression (U.S. National Library of Medicine, 2019). It is generally administered as a once-daily oral dose in the morning. The evidence demonstrates about 3.6 kg of additional weight loss during short-term clinical trials of up to 24 weeks when compared with lifestyle modifications alone (Apovian et al., 2015). Most commonly seen adverse effects are palpitations, tachycardia, increased blood pressure, pulmonary hypertension, overstimulation, insomnia, dry mouth, and gastrointestinal (GI) disturbances (U.S. National Library of Medicine, 2019). It is contraindicated in patients with a history of cardiovascular disease, hyperthyroidism, history of drug abuse, pregnancy, and those taking monoamine oxidase inhibitors (MAOIs). Its use is not recommended in patients with hypertension. Because of its stimulant-like property, this agent is defined as a schedule C-IV drug per the DEA's controlled substance act. Clinical utility of short-term agents in general is limited, given the fact that obesity management should be a chronic approach; however, phentermine remains the most widely prescribed weight management therapy and is usually prescribed for long-term use despite FDA approval for short-term use and lack of long-term data from clinical trials (Bray & Ryan, 2014).

Orlistat (Xenical, Alli)

Orlistat is approved by the FDA for chronic weight management that targets a different pathophysiology of obesity (U.S. National Library of Medicine, 2019). High intake of dietary fat is associated with development of obesity. Lipase enzyme is responsible for degradation of dietary fats and absorption of long-chain triglycerides. Orlistat is a lipase inhibitor that helps reduce absorption of these dietary fats by inhibiting GI lipases and therefore reducing caloric consumption. The oral product is available in two different strengths: 60 mg tablet as an over-the-counter (OTC) product called Alli and 120 mg tablet as a prescription-only product called Xenical. Given its mechanism of action, the drug works best when taken three times a day with meals that contain fat. As much as 30% reduction in fat absorption

Table 2. Summary of FDA-Approved Pharmacologic Agents for Weight Management

Brand Name (Generic Name)	Mechanisms for Weight Loss	Common Side Effects	Weight Loss Efficacy[a]; Duration of Studies	Clinical Pearls
Agent approved for short-term use				
Adipex-P, Lomaira (phentermine)	Increases energy expenditure and appetite suppression	Palpitations, tachycardia, increased blood pressure, insomnia, dry mouth, overstimulation	3.6 kg; 2–24 weeks	Schedule C-IV Do not use in patients with cardiovascular disease, hypothyroidism, a history of drug abuse, and pregnancy Not recommended in patients with hypertension
Agents approved for long-term use				
Xenical, Alli (orlistat)	Blocks absorption of dietary fats	Soft stools, flatulence, fecal urgency, fecal incontinence, abdominal pain	2.9–3.4 kg; 1 year	Gastrointestinal side effects subside after the first couple of months Supplement with fat-soluble vitamins Certain drug interactions require separating its administration by 4 hours
Belviq (lorcaserin)	Suppresses appetite and improves satiety	Headache, dizziness, fatigue, nausea, dry mouth, constipation Hypoglycemia in patients with diabetes	3.6 kg; 1 year	Monitor for serotonin syndrome when combined with other drugs that work in the serotonin system Monitor blood glucose in patients with diabetes
Contrave (naltrexone and bupropion)	Suppresses appetite	Headache, constipation, diarrhea, nausea, vomiting, dizziness, insomnia, dry mouth	4.9 kg; 1 year	Do not take with high fat-containing foods Do not use in patients with uncontrolled hypertension Monitor heart rate and blood pressure at baseline and during therapy Monitor blood glucose in patients with diabetes
Qsymia (phentermine and topiramate)	Suppresses appetite, improves satiety, and increases energy expenditure	Dizziness, paresthesia, dysgeusia, insomnia, dry mouth	6.6–8.6 kg; 1 year	Follows a specific titration Monitor heart rate, blood pressure, electrolytes, and serum creatinine Monitor blood glucose in patients with diabetes
Saxenda (liraglutide)	Suppresses appetite and improves satiety	Nausea, vomiting, constipation, abdominal pain, diarrhea, dyspepsia	5.8 kg; 1 year	Teach injection administration technique and proper dose titration Monitor heart rate, renal function, and behavior changes Monitor blood glucose in patients with diabetes; may need adjustment of other antihyperglycemic drugs

[a]When compared with lifestyle modifications alone.

has been observed with the prescription strength orlistat. Studies show that 1 year of treatment with prescription strength orlistat can provide additional weight loss of 2.9–3.4 kg compared with lifestyle modifications alone (Apovian et al., 2015). Evidence also shows that orlistat decreased the rate of progression to Type 2 diabetes, reduced the number of antihyperglycemic medications taken by patients with diabetes, and improved glycemic and lipid control when used along with the reduced diet therapy (McClendon, Riche, & Uwaifo, 2009; Torgerson, Hauptman, Boldrin, & Sjostrom, 2004; Yanovski & Yanovski, 2014). Most common side effects of orlistat include GI complaints such as soft stools, flatulence, fecal urgency, fecal incontinence, and abdominal pain and are reported in up to 80% of patients taking prescription strength orlistat (U.S. National Library of Medicine, 2019). These complaints are common in the first couple of months of therapy but

generally subside thereafter. Reducing the amount of fat in meals can help limit these side effects. Supplementation with multivitamins should be considered, as it impairs absorption of fat-soluble vitamins such as vitamins A, D, E, and K. Patients should be educated to not double up the OTC dose as (a) it is against the labeled instructions and (b) taking it such without provider supervision can result into increased side effects. Orlistat, directly or indirectly, interacts with multiple other drugs such as warfarin, levothyroxine, amiodarone, lamotrigine, gabapentin, and valproic acid. To mitigate some of the absorption-related interactions, separating these medications from orlistat by at least 4 hours should be recommended. Rare postmarketing reports for liver failure have been reported; however, causality has not been established (U.S. National Library of Medicine, 2019). Patients should be advised to report signs of liver insufficiency, such as yellowing of skin or sclera, malaise, nausea, vomiting, or abdominal pain, to their healthcare providers. Routine monitoring for liver enzymes is not recommended, however.

Lorcaserin (Belviq)

Lorcaserin is a selective serotonin ($5\text{-}HT_{2c}$) receptor agonist approved for chronic weight management (U.S. National Library of Medicine, 2019). It stimulates serotonin receptors in the hypothalamus, which results in appetite suppression leading to decreased caloric intake and improved satiety. This schedule C-IV product is available by prescription as regular release and extended release oral formulations taken as 10 mg twice daily or 20 mg once daily, respectively. Studies show that 1 year lorcaserin treatment provided 3.6 kg of additional weight loss when compared with lifestyle modifications alone (Fidler et al., 2011; O'Neil et al., 2012; Smith et al., 2010). These three studies also show improvement in fasting glucose, glycated hemoglobin or hemoglobin A_{1c} (HbA_{1c}), insulin, total cholesterol, low-density lipoprotein cholesterol, and triglycerides with lorcaserin therapy compared with placebo in patients with and without diabetes. Based on clinical data, the FDA label indicates discontinuation if 5% weight loss from baseline is not achieved by 3 months of therapy as patient will likely not receive additional benefit (U.S. National Library of Medicine, 2019). Most common adverse events associated with lorcaserin are headache, dizziness, fatigue, nausea, dry mouth, and constipation. In addition to these, hypoglycemia, back pain, and cough were observed in patients with diabetes using lorcaserin. Theoretical risk of cardiac valvulopathy is present with lorcaserin use, but clinical trials did not show a higher risk of this adverse event when compared with placebo. Cautious use is suggested in patients with congestive heart failure, as the risk of cardiac valvulopathy increases in these patients. Given that lorcaserin increases serotonin, when combined with other drugs such as selective serotonin reuptake inhibitors—used for the treatment of depression and other mental health conditions—there is an increased risk of serotonin syndrome. Other rare adverse effects include priapism, psychiatric disorders including depression, suicidal thoughts, euphoria, and dissociation, and cognitive impairment. In patients with diabetes, lorcaserin has been shown to decrease blood glucose and therefore increased monitoring of blood glucose in these patients should be recommended.

Naltrexone and Bupropion (Contrave)

This combination product was approved for chronic weight management by the FDA in 2014 (U.S. National Library of Medicine, 2019). Naltrexone is an opioid antagonist used for opioid reversal, whereas bupropion is a norepinephrine and dopamine reuptake inhibitor mainly used to treat depression. The exact mechanism by which it reduces weight is unknown, but the resulting effect of the combination is appetite suppression. This oral formulation also follows a titration schedule starting with one tablet a day and titrating to two tablets twice daily. Doses should be avoided along with high fat-containing meals, as it can result in an increased absorption of the drug and thus increased risk of adverse effects. A systematic review reports an average additional weight loss of 4.9 kg over 1 year where the combination product was compared with placebo (Yanovski & Yanovski, 2015). Improvements in high-density lipoprotein, triglycerides, glucose, and insulin were also noted with this combination product when compared with placebo (Apovian et al., 2013; Greenway et al., 2010; Hollander et al., 2013; Wadden et al., 2011). Similar to other weight management agents, its use should be discontinued if at least 5% weight loss from baseline has not been achieved by 3 months of therapy (U.S. National Library of Medicine, 2019). Most common adverse effects are headache, constipation, diarrhea, nausea, vomiting, dizziness, insomnia, and dry mouth. Mild increases in heart rate and blood pressure were noted in the first 3 months of therapy with this combination as compared with placebo and therefore its use is contraindicated in patients with uncontrolled hypertension. Monitoring of these parameters at baseline and during the therapy is recommended. Even though rare, hepatotoxicity may occur due to the naltrexone component; patients should be advised to report any signs and symptoms of acute hepatitis with its use. Given the bupropion component, risk for seizure, suicidal thoughts and behavior, and angle-closure glaucoma have been added to the label. Patients with diabetes taking this combination product along with other antihyperglycemic agents should be advised to monitor blood glucose closely as the combined use may result in hypoglycemia. Several other drug interactions also exist when its use is combined with other neuropsychiatric agents, such as antidepressants. Its use with opioids, MAOIs, alcohol, benzodiazepines, barbiturates, and antiepileptics is contraindicated.

Phentermine and Topiramate (Qsymia)

This combination product is available as an extended release oral formulation and is approved for chronic weight management (U.S. National Library of Medicine, 2019). In addition to norepinephrine-mediated appetite suppression and energy expenditure via phentermine, topiramate—an antiepileptic drug—works through multiple possible mechanisms to provide appetite

suppression and satiety enhancement; its exact mechanism is unknown, however. The once daily oral formulation is started at a low dose and requires a titration schedule to reach recommended daily dose of 3.75/23 mg. After 14 days, it can be further increased to the highest possible dose of 7.5/46 mg. If 5% weight loss from baseline is not achieved by 3 months of therapy following proper titration, per the FDA label, the dose should be gradually tapered down to eventually discontinue the use, as further benefit is unlikely. At 1 year, this combination product provides 6.6 and 8.6 kg of additional weight loss at recommended and highest dose, respectively, when compared with lifestyle modifications alone (Gadde et al., 2011). The evidence also suggests decreased metabolic parameters such as blood pressure, cholesterol, and glucose with its use (Allison et al., 2012; Gadde et al., 2011). Most common side effects include dizziness, paresthesia, dysgeusia, insomnia, and dry mouth (U.S. National Library of Medicine, 2019). Some rare adverse effects include increased heart rate, suicidal ideation and behavior, mood disorders, insomnia, cognitive impairment, metabolic acidosis, seizures, and hyperhidrosis. Additional monitoring includes heart rate, blood pressure, electrolytes, especially serum potassium, and serum creatinine. Patients with diabetes may require additional monitoring of blood glucose as it can cause hypoglycemia.

High-Dose Liraglutide (Saxenda)

High-dose liraglutide was FDA approved for chronic weight loss management in 2014 (U.S. National Library of Medicine, 2019). Regular dose liraglutide has indication for treatment of Type 2 diabetes mellitus. Endogenous glucagon like peptide-1 (GLP-1) is released from the stomach upon food digestion. When it stimulates GLP-1 receptors in the brain, it induces satiety and causes appetite suppression. Exogenous administration of high-dose liraglutide involves a once daily subcutaneous injection without regard to meals. The 5-week titration period begins with a starting dose of 0.6 mg, which is increased to a final 3 mg dose using 0.6 mg increments to help minimize GI side effects. Per the label, if at least 4% weight loss from baseline has not been achieved by the end of Week 16, liraglutide should be discontinued as further weight reduction is unlikely. Unlike all the other oral agents for weight management, this is a parenteral product and therefore requires added education regarding proper administration, what sites to administer the medication, storage, and appropriate sharps disposal. In clinical trials, the high-dose liraglutide provided additional weight loss of up to 5.8 kg over 1 year when compared with lifestyle modifications alone in patients with or without diabetes (Davies et al., 2015; Pi-Sunyer et al., 2015). As expected, more patients achieved target HbA_{1c} goals with high-dose liraglutide than with placebo (Davies et al., 2015). Most common adverse effects revolve around GI complaints such as nausea, vomiting, constipation, abdominal pain, diarrhea, and dyspepsia, which can be minimized with slower titration (U.S. National Library of Medicine, 2019). Elevation of heart rate has been noted in clinical trials; however, the clinical impact is insignificant as this elevation was two to three beats per minute. Heart rate should be monitored at routine intervals for this reason. Although rare, cases of pancreatitis, including hemorrhagic and necrotizing pancreatitis, have been reported; patients should be educated regarding signs and symptoms of acute pancreatitis. Given its effect on blood glucose lowering, it can cause hypoglycemia when used with other antihyperglycemic agents such as insulin and sulfonylurea; dose adjustment in the latter agents may be warranted. These patients should be educated to employ proper blood glucose monitoring. Liraglutide is contraindicated in patients with a personal or family history of medullary thyroid carcinoma, C-cell thyroid tumor, or multiple endocrine neoplasia syndrome type 2. The label also includes warning for renal impairment and suicidal behavior or ideation. Monitoring renal function and behavior changes during the therapy is therefore important.

Other Approaches

As reviewed, there are various types of pharmacotherapeutic agents approved for medical weight management that are FDA indicated. Off-label use of certain products such as topiramate, metformin, phentermine long-term therapy, zonisamide, and exenatide has been seen in clinical practice despite recommendations against their use (Apovian et al., 2015). In addition to off-label uses, weight loss dietary supplements such as green tea, caffeine, ephedrine, yohimbine, and *Garcinia cambogia* are used by approximately 15% of adult consumers in the United States (National Institute of Health, 2019). The use of such products should be discouraged because of the lack of clinical evidence for safety and efficacy, potential for drug-drug and drug-disease interactions, and unreliable product content. Overall initial goal for therapy is to achieve clinically significant weight loss of 5%–10% over the first 6 months, as this has shown to improve various metabolic parameters as well as decrease cardiovascular disease risk (Jensen et al., 2014). Patients who fail to achieve this goal with one approved agent can try another approved agent. Those who fail pharmacotherapy or those with a BMI of 35 or greater with one comorbidity or a BMI of 40 or greater should be referred to a bariatric surgery specialist, as bariatric surgery is the appropriate weight management modality for them (Apovian et al., 2015; Jensen et al., 2014).

Nursing Implications

Weight management should be a chronic approach employing a multidisciplinary team involving physicians, nurses, pharmacists, dietitians, psychologists, and behavioral experts. Nurses are likely to encounter patients who are actively trying or have future plans to manage their weight. Nurses can provide constant motivation and education needed for patients to follow proper lifestyle modifications such as diet and exercise, monitor adherence to both lifestyle and pharmacotherapeutic interventions, and help monitor the therapeutic outcomes. Because most of the pharmacotherapeutic agents have common and serious side effects, nurses can also help monitor these side effects and provide necessary guidance to mitigate them. This involvement can occur on various

different levels including individual patient interactions, group education classes, as well as community- and online-based support groups. A British study surveyed about 400 nurses on self-efficacy and practice relating to adult weight management (Zhu, Norman, & While, 2013). Most nurses believed that weight management should be a multidisciplinary approach and they were appropriate health professional to contribute in such multidisciplinary teams. In addition, nurses who accepted their role in weight management and valued teamwork in caring for these patients reported higher levels of self-efficacy.

Conclusion

Obesity is a chronic condition highly prevalent in the U.S. population that can lead to further cardiovascular morbidity and mortality. The management of this condition should also be chronic in nature employing various modalities such as reduced calorie diet, increased physical activity, behavioral modifications, as well as treatment with approved pharmacotherapy agents. This management should be driven by a multidisciplinary healthcare provider team where nurses can play an integral role in patient motivation, education, and monitoring of therapeutic outcomes.

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For additional continuing nursing education activities on orthopaedic nursing topics, go to nursingcenter.com/ce.

Calendar

National Offerings

May 30–June 2, 2020: NAON's 40th Annual Congress, Pittsburgh, PA

NAON Member Benefit Webinar Series

April 29, 2020: Tips and Tricks for the Orthopedic Nurse on the Front Lines

Member Benefit Webinars are posted on the NAON website as they are scheduled.

Upcoming Live Orthopaedic Nursing Review Courses

April 27, 2020–FirstHealth Moore Regional Health Center-Pinehurt, NC

May 18, 2020–University of Rochester-Rochester, NY

May 22, 2020–BayCare-Tampa, FL

Interested in hosting a review course at your facility? Consider our newly launched Custom Bone Up programs! NAON is excited to offer a revamped Bone Up program, which provides a wealth of nursing education opportunities at special pricing for your facility. Each Bone Up bundle is specifically designed to offer NAON membership, online and in-person education, publications, Congress registration and more, combined in a way that makes the most sense for you and your team.

Upcoming Live Orthopaedic Nursing Round-table Course

April 28, 2020–St. Charles Health-Bend, OR

Upcoming NAON Education Product Releases

New–Orthopaedic Knowledge Self-Assessment Modules

Spring 2020: Revised NAON Practice Points

Ongoing in 2020: Update/revision of select NAON Position Statements