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A Retrospective Comparative Analysis on the Effectiveness of Pharmacologic Weight Loss

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The document mentioned above has been reviewed and accepted by the student's advisor, on behalf of the advisory committee, and by the Assistant Dean for MSN and DNP Studies, on behalf of the program; we verify that this is the final, approved version of the student's DNP Project including all changes required by the advisory committee. The undersigned agree to abide by the statements above.

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DNP Final Project Report

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Dedication

This work and my DNP Project is dedicated to my family who instilled in me the value of education and hard work. Thank you for being my support system through all the ups and downs over the past five years. Thank you, God, for letting me make it through this program. Meme, you talked me in to Graduate school and encouraged me to further my education. You pushed me (sometimes literally) every step on the way and made sure I reached my goal. Thank you for being my temporary roommate, graduate financial supporter, and best friend. Thank you to my parents who have supported me through this long journey and dog-sat for me A LOT so I could work and go to school. You instilled in me hard working values, good principles, and beliefs which made me who I am today. Thank you to the rest of my family for supporting me and encouraging me, feeding me, and loving me. Thank you to my dogs for being my companions on the long nights writing papers, walking buddies when I needed a study break, and snuggle buddies when I needed to rest. Thank you to my best friends who supported me in so many ways throughout these past five years. Thank you for the quick but forever memorable vacations, dinner dates, and motivation. Thank you to my coworkers who supported my education endeavors and put up with me along the way. My entire graduate program and compilation of my hard work is dedicated to everyone who has loved and supported me and to my future patients. I hope to truly make a difference in your life.

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Abstract

PURPOSE: Obesity costs the U.S. roughly $147 billion in health care spending annually. There has been a call for healthcare providers to initiate all possible weight loss interventions. One treatment strategy not used to its fullest potential is that of prescribing antiobesity medications. The purpose of this project was to examine and evaluate the effectiveness of three common weight loss medications used in the treatment of obesity, including discussion and recommendations.

METHODS: This project was a single-center retrospective study comparing three different groups of patients seen at a rural weight loss clinic. The sample consisted of 84 patients seen between September 2014 to September 2017. Three groups taking Adipex, Adipex + Contrave, and Apidex + Saxenda were evaluated for effectiveness on weight loss, BMI, and waist circumference. Compliance to medications, diet, and exercise were evaluated.

RESULTS: Each medication group proved to be effective in treating obesity. On average, patients taking Adipex had 7.2% weight loss, Adipex + Contrave had 7.2% weight loss, and Adipex + Saxenda averaged 9.1% weight loss. Compliance to diet and exercise was a determinant for weight loss success. Those that did not comply to the medication regimen or a diet and exercise plan did not decrease obesity measures.

CONCLUSION: Pharmacotherapy is an adjunctive therapy to diet and exercise. No differences in the effectiveness of medication between groups was found; however, each medication was statistically proven to be effective in obesity reduction. Adipex, while proving just as effective as combination therapy, is the most affordable and when applicable should be considered along with diet and exercise for those seeking weight loss.

A Retrospective Comparative Analysis on the Effectiveness of Pharmacologic Weight Loss

Introduction

In a recent survey, Americans ranked obesity as the top health concern in the country (State of Obesity, 2017). As obesity-related health issues continue to escalate, Americans seek to reverse the trend by taking an interest in personal health and wellness by reaching for the "all natural" or "organic" labels, hitting the gym, and fad dieting (Walsh, 2015). Perhaps this trend is why 502 billion dollars are spent by consumers on prevention and wellness products (e.g. vitamins, nutritional supplements, over the counter weight loss supplements, and fortified foods) (Accenture, 2014). Health and wellness has been called "the next trillion-dollar marketplace" and projected to grow 50% over the next five years (Accenture, 2014; Cloos et al., 2012). There is a growing use of anti-obesity medications to help those who simply are not successful in losing weight. The purpose of this project was to provide a retrospective analysis comparing the effectiveness of three weight loss medications on weight, body mass index (BMI), and waist circumference used in one weight loss clinic.

Background & Scope

Global

According to the World Health Organization (WHO) (2018), an estimated 2.8 million people die each year secondary to being overweight or obese. The prevalence of overweight and obesity is highest in North America (62% overweight, 26% obese) and lowest in South East Asia (14% overweight, 3% obese) (WHO, 2018). Between 1980 and 2014, obesity rates more than doubled worldwide (Manchi & de Melo, 2017). As of 2014, the WHO reported more than 1.9 billion adults over age 18 were overweight (38% men, 40% women); of those, over 600 million were obese (11% men, 15% women) (2016).

National

With an estimated 150 billion dollars spent on obesity related health care annually, and billions more in production loss, obesity is now considered the most prevalent chronic disease in the United States (Kim & Basu, 2016; Winterfield & Cauchi, 2014). As of 2011, a projected cost of over 11 billion dollars was spent on medical costs for obese adults in the U.S. (The State of Obesity, 2015). Obesity rates exceeded 35% in five states (West Virginia, Mississippi, Alabama, Arkansas, and Louisiana); nationally, nearly 8% of adults fall into the extremely obese (BMI >40) category (State of Obesity, 2017). Interestingly, in 1985, no state had an adult obesity rate exceeding 15% and in 2006, only Mississippi was above 30% (State of Obesity, 2017).

In Table 1, gender demographics for obesity are outlined (see Table 1). Statistically significant differences were seen in obesity rates and ethnicity. The highest prevalence is noted in the Black community followed by Hispanics and then Caucasians. Level of education and income have been recognized as factors in the prevalence of obesity. Of those who did not graduate high school, 33% were found to be obese compared to 22% of those who went to college or technical college (State of Obesity, 2017). More than 33% of adults who earned less than 15,000 dollars per year were obese compared to 24.5% who earned at least 50,000 dollars per year (State of Obesity, 2017).

Table 1.

National Obesity Rates, 2017

National Obesity Rates, 2017			
	Men & Women	**Men**	**Women**
Overall	38%	35%	40.4%
Blacks	57.2%	38%	38%
Latinas	46.9%	37.9%	Unknown
Whites	38.2%	34.7%	34.7%
Asians	12.4%	Unknown	Unknown

Note: data from the State of Obesity Annual Reports. Retrieved from http://www.stateofobesity.org/obesity-rates-trends-overview/ (2017).

The 2017 State of Obesity Annual Report recorded a decline in obesity rates for 2016 in four states (Minnesota, Montana, New York, & Ohio). This is the first time a reduction has been seen since data collection; yet, obesity remains one of America's most prevalent health problems. The etiology centers on the American lifestyle when one evaluates reported current diet and exercise patterns. Less than half of Americans meet U.S. aerobic guidelines, greater than 70% do not meet the recommended daily servings of fruits or vegetables, approximately 49% of adults drink a sugar-sweetened beverage per day, and most exceed recommended levels of solid fats, added sugar, and sodium (State of Obesity, 2017).

Local. Kentucky is currently ranked seventh for highest rate of obesity in the country with a rate of 34.2% (State of Obesity, 2017). Kentuckians living in rural areas, particularly the Appalachian region, have a higher prevalence of being overweight or obese, and have more obesity-related health conditions than those living in other state rural regions (Schoenberg et al, 2013). Alarmingly, between 2008-2010, two in three adult Kentuckians were overweight

(67.1%) and three in ten (31.5%) were obese (Walsh et al., 2012). Seven in ten (70.1%) of Appalachian adults were overweight and one in three (34.6%) were obese (Walsh et al., 2012). According to the State of Obesity Annual Reports (2012), those living in the Appalachian region have experienced an increase in the prevalence of obesity in the past eight years.

The Appalachian communities are socioeconomically impoverished and have decreased access to health care. There is a higher prevalence of smoking, poor eating habits, inactivity, and mental health disorders (Schoenberg, Huang, Seshadri, & Tucker, 2015). According to the most recent data, 28.4% of those living in the Appalachian region are physically inactive (Marshall & Alcalde, 2017). As of 2011, 17% of Kentuckians forego medical care due to cost and 16% have no personal health care provider (Walsh et al., 2012).

Affordability of high quality food, insufficient transportation, and geographic locations were described by Appalachian residents as some of the greatest barriers for battling obesity (Schoenberg et al., 2015). One resident from Harlan county stated, "When McDonald's opened, their opening day here surpassed any other openings in the United States." (Schoenberg et al., 2015). Many Appalachian residents know a "Big Mac" may not be the healthiest option but will accept the consequences due to convenience or the marketing of the item influences them (Schoenberg et al., 2015). This information is alarming and demonstrates the need for rural health care and obesity education.

Obesity Risks

With obesity and associated factors costing healthcare billions annually, and coupling this with its comorbidities and chronicity, obesity is now considered a disease by healthcare professionals (Garvey et al., 2016). Morbidity and mortality of obesity-related conditions make

obesity a necessary target for intervention. Clearly healthcare providers must be fully engaged in helping patients reach a healthy weight and use all avenues for treatment (Garvey et al., 2016).

The obesity epidemic raises the need for preventive care. Obesity alone is a major risk factor in cardiovascular, orthopedic, and metabolic disorders (Emmett & Chandra, 2015). Weight-related complications include: type 2 diabetes, dyslipidemia, hypertension, cardiovascular disease, nonalcoholic fatty liver disease, polycystic ovary syndrome, female infertility, male hypogonadism, obstructive sleep apnea, asthma/reactive airway disease, osteoarthritis, urinary stress incontinence, gastroesophageal reflux disease, and depression (Garvey et al., 2016). Each of these conditions can be medically managed. However, with clinically significant weight reduction, each of these comorbidities could be remedied without medication (Garvey et al., 2016).

Bias

Obesity is a major and growing problem, but how do you convince society of the need for change? Emmett and Chandra (2015) conducted a study examining people's perception of how great a problem obesity is in the U.S.; a total of 692 Americans replied to surveys. The majority (94.4%) were aware that obesity is a major and growing problem (Emmett & Chandra, 2015). This study found that people correlated obesity with diet (p. 96). Making people aware of the consequences and causes of obesity is the first step in addressing this epidemic.

An unfortunate consequence many obese adults face is that of weight stigmatization (Puhl, Quinn, Weisz, & Suh, 2017). Weight stigmatization, or negative societal devaluation of people based of their excess body weight, is a form of prejudice (Puhl et al., 2017). Recent studies show a relationship between obesity and psychological disorders (Collins, Meng, & Eng, 2016). Numerous studies report obese individuals claiming lower quality of life, decreased life

satisfaction, anxiety, and higher incidence of depression (Collins et al., 2016; Lin et al., 2013). Remarkably, the correlation between obesity and psychological disorders appears bidirectional; psychological disorders may develop obesity and obese may develop psychological disorders (Collins et al., 2016).

Vast instances of weight derogatory comments, verbal aggression, and cyber-bullying occur daily on social media (Brun, McCarthy, McKenzie, & McGloin, 2014; Chou, Presin, & Kunath, 2014). Meta-analyses show weight bias has negative impacts on job related outcomes (hiring, salary, promotion status) (Roehling, Pichler, & Bruce, 2013; Vanhove & Gordon, 2014). Evidence validates the correlation between weight stigmatization, adverse health behaviors, and outcomes leading to weight gain such as increased risk of depression, stress, binge eating, or reduced physical activity (Puhl et al., 2017). Currently, in the United States, obese individuals have little to no legal protection against weight-based discrimination (Pearl, 2018). There needs to be strategies to decrease weight bias and discrimination in the workplace, schools, and media (Pearl, 2018).

Constant media attention about obesity-related topics continue to invade broadcasting. The healthcare community has been found to harbor negative views about those who are overweight or obese (Puhl, 2017). Fortunately, there does seem to be some movement by primary care providers (PCPs) in addressing obesity. According to a study by Mehta et al. (2012), PCPs were 2.38 times more likely to provide obesity management compared to specialists (i.e. Gastroenterologists, Endocrinologists, Gynecologists). Further, patients who had preventive visits and/or chronic visits were more likely to receive obesity management over patients who only had acute visits (Mehta et al., 2012). Mehta et al. (2102) reports that more time spent with a PCP, the number of comorbid conditions, and a BMI $\geq$40 significantly

increased the likelihood of receiving obesity management. Elderly or those who smoke were less likely to receive obesity treatment (Mehta et al., 2012). Other studies report health care professionals as having less respect for obese patients believing they are unmotivated, lazy, and unlikely to be compliant with treatment recommendations (Phelan et al., 2015; Puhl, Phelan, Nadglowski, & Kyle, 2016).

Stakeholders

There are a number of stakeholders seeking to address the obesity epidemic. In 2013, governmental agencies on the federal, state, and local level began to institute changes that would address the growing problem of obesity. School food programs, propositioning initiatives to tax or ban certain foods and beverages, and proposed changes in nutrition labeling have been directed at improving American's nutrition (Slavin, 2015). These address primary prevention, which is easier than addressing obesity.

Countless health care organizations have developed programs of research focused on new technology (bariatric surgery), medications, and policy advancements for decreasing obesity. The American Association of Clinical Endocrinologists (AACE) Board of Directors and American College of Endocrinology (ACE) Board of Trustees published standardized clinical practice guidelines (CPGs). Each have provided recommendations for comprehensive medical care of patients with obesity based on a diligent review of the clinical evidence (Garvey et al., 2016).

Current Practice Guidelines & Theory

AACE/ACE Guidelines

The CPGs for comprehensive medical care of patients with obesity include evidence for definitions, goals, and methods for phases of prevention in chronic disease. The CPGs include

an executive summary of 123 clinical practice recommendations which cover the spectrum of obesity management (Garvey et al., 2016). The core recommendations for medical care of patients with obesity include three phases of chronic disease prevention and treatment (Garvey et al., 2016). These three phases (primary, secondary, and tertiary interventions) should be the basis of the modality and intensity of obesity interventions (Garvey et al., 2016).

Three phases. Phases of prevention include primary, secondary, and tertiary. Primary prevention discusses ways to prevent the progress of overweight and obesity. Secondary prevention considers ways to prevent further weight gain and weight-related complications in patients who are overweight or obese. Tertiary prevention examines ideas of treatment with weight-loss therapy to decrease weight-related complications and prevent advancement of disease (Garvey et al., 2016, see table 2).

Table 2.

Three phases of Prevention in Obesity as a Chronic Disease

General Practices in Chronic Disease in Obesity		
Phase of Intervention	Definition and Goals	Methods of Prevention
Primary Prevention	○ Prevent the development of overweight and obesity	○ Eliminate risk factors ○ Educate the public ○ Promote healthy eating and regular physical activity
Secondary Prevention	○ Prevent future weight gain and the development of weight-related complications in patients with overweight or obesity	○ Screen using Body Mass Index (BMI) annually ○ Diagnose using BMI and evaluation for complications ○ Treat with lifestyle/behavioral intervention with/without weight-loss medications

Tertiary Prevention	○ Treat with weight loss therapy to eliminate weight-related complications ○ Prevent disease progression	○ Treat with lifestyle/behavioral interventions plus weight-loss medications ○ Consider bariatric surgery

Note: data from American Association of Clinical Endocrinologists and American College of Endocrinology clinical practice guidelines for comprehensive medical care of patients with obesity- Executive Summary, by Garvey et al. Retrieved from doi: 10.4158/EP161365.G (2016).

BMI/Waist Circumference. According to Garvey et al. and the AACE/ACE CPGs, body mass index (BMI) is the best anthropomorphic criteria for confirming an excess in adiposity (2016). Diagnosing individuals as being overweight or obese in the clinical setting is based on BMI. BMI is constructed using the formula weight in kilograms divided by height in meters squared (BMI= wt in kg/ht in m^2). Clinical evaluation must be considered when using BMI, taking in to account the age, gender, ethnicity, fluid status, and muscularity (Garvey et al., 2016). Individuals are considered overweight with a BMI of 25-29.9 kg/m^2 and obese with a BMI of $\geq$ 30 kg/m^2 (Garvey et al., 2016).

Other methods of measure for adiposity such as air/water displacement or dual-energy x-ray absorptiometry may be used if BMI and physical exam require further evaluation; cost, availability, and lack of validity do not support these methods (Garvey et al., 2016). In addition to BMI, adiposity-related disease risk should be evaluated for every patient based on waist circumference (Garvey et al., 2016). In the United States, indication of increased risk of disease are waist circumference $\geq$ 40 inches ($\geq$ 102 cm) in men and $\geq$ 35 inches ($\geq$ 88 cm) in women (Garvey et al., 2016, see table 3).

Table 3.

Classification of Overweight and Obesity by BMI and Waist Circumference

Classification of Overweight and Obesity by BMI and Waist Circumference per AACE/ACE CPG				
Classification	**BMI**		**Waist**	
	BMI (kg/m^2)	**Comorbidity Risk**	**Waist Circumference and Comorbidity Risk**	
			Men ≤40 in (102 cm) Women ≤35 in (88 cm)	Men >40 in (102 cm) Women >35 in (88 cm)
Underweight	<18.5	Low		
Normal weight	18.5-24.9	Average		
Overweight	25-29.9	Increased	Increased	High
Obese class I	30-34.9	Moderate	High	Very High
Obese class II	35-39.9	Severe	Very High	Very High
Obese class III	≥40	Very Severe	Extremely High	Extremely High
Abbreviations: BMI= body mass index; in= inches				

Note: data from American Association of Clinical Endocrinologists and American College of Endocrinology clinical practice guidelines for comprehensive medical care of patients with obesity- Executive Summary, by Garvey et al. Retrieved from doi: 10.4158/EP161365.G (2016).

Weight Related Complications & Therapeutic Benefits of Weight Loss. After initial evaluation, and identification of weight-associated comorbidities there should be ongoing follow up to monitor for changes in adiposity and complications (Garvey et al., 2016). In Table 4, the effect of weight loss on known comorbidities is outlined (see Table 4). Weight loss can be an effective treatment of weight-related conditions with significant changes seen with just a 5% weight loss (Garvey et al., 2016).

Table 4.

Treatment Goals Based on Diagnosis in the Medical Management of Patients with Obesity

Treatment Goals Based on Diagnosis in the Medical Management of Patients with Obesity					
Tertiary Prevention					
Classification	Anthropometric Component	Clinical Component		Weight Loss Goal (%)	Clinical Goals
Overweight or Obesity	BMI ≥25 kg/m^2	Metabolic syndrome		10%	Prevention of T2DM
		Prediabetes		10%	Prevention of T2DM
		T2DM		5% to ≥ 15%	○ Reduction in A1C ○ Reduction in number and/or doses of glucose lowering medications ○ Diabetes remission especially when diabetes duration is short
		Dyslipidemia		5% to ≥ 15%	○ Lower triglycerides ○ Raise HDL-c ○ Lower non-HDL-c
		Hypertension		5% to ≥ 15%	○ Lower systolic and diastolic BP ○ Reductions in number and/or doses of antihypertensive medications
		Nonalcoholic fatty liver disease (NASH)	Steatosis	5% or more	Reduction in intrahepatocellular lipid
			Steatohepatitis	10% to 40%	Reduction in inflammation and fibrosis
		Polycystic ovary syndrome		5% to 15% or more	○ Ovulation ○ Regularization of menses ○ Reduced hirsutism ○ Enhanced insulin sensitivity ○ Reduced serum androgen levels
		Female infertility		10% or more	○ Ovulation ○ Pregnancy and live birth
		Male hypogonadism		5% to 10% or more	Increase serum testosterone
		Obstructive sleep apnea		7% to 11% or more	○ Improved symptomatology ○ Decreased apnea-hypopnea index

		Asthma/reactive airway disease	7% to 8% or more	○ Improvement in forced expiratory volume at 1 second ○ Improved symptomatology
		Osteoarthritis	○ ≥10% ○ 5% to 10% or more when coupled with exercise	○ Improvement in symptomatology ○ Increased function
		Urinary Stress Incontinence	5% to 10% or more	Reduced frequency of incontinence
		Gastroesophageal reflux disease	10% or more	Reduced symptom frequency and severity
		Depression	Uncertain	○ Reduction in depression symptomatology ○ Improvement in depression scores

Abbreviations: A1C= hemoglobin A1C; BMI= body mass index; BP= blood pressure; HDL-c= high-density lipoprotein cholesterol; T2DM= type 2 diabetes mellitus.

Note: data from American Association of Clinical Endocrinologists and American College of Endocrinology clinical practice guidelines for comprehensive medical care of patients with obesity- Executive Summary, by Garvey et al. Retrieved from doi: 10.4158/EP161365.G (2016).

Lifestyle & Behavioral Therapy and Plan. Along with evaluation, the AACE/ACE CPGs recommend a structured lifestyle intervention program designed for weight loss (2016). This should include healthy meal planning, physical activity, and behavioral interventions (Garvey et al., 2016). According to Garvey et al., a reduced total energy (caloric) intake should be the main component for interventional weight-loss. Meal plans should include a daily reduction of 500-750 kcal. Dietary considerations can include the Mediterranean, DASH, low-carb, low-fat, high protein, or vegetarian diets, and/or meal replacements. Expertise from a dietician or health educator is optimal (Garvey et al., 2016). The CPGs do not recommend one specific diet over another. Diets that fit the individual's lifestyle and likes/dislikes are important to take in to consideration to avoid barriers to weight loss.

Reduction of sedentary lifestyle with an individualized program based on goals, preferences, and limitations should be discussed with an expert (trainer, coach, physical/occupational therapist) when possible (Garvey et al., 2016). The AACE/ACE CPGs recommend aerobic physical activity progressing to >150 minutes/week 3 to 5 days per week along with resistance exercise involving major muscle groups 2 - 3 times/week (2016). Given the current level of exercise reported by the vast majority of those who are obese, there should be a gradual progression to the recommended time of exercise.

Educational material on behavioral modification ought to be reviewed with a health educator, clinician, behaviorist, or clinical psychologist/psychiatrist (Garvey et al., 2016). These materials should include helpful strategies in adhering to diet and exercise recommendations and self-monitoring of their weight loss strategies. Patients are encouraged to set reasonable goals and be assisted in problem solving and coping as they engage in their weight loss journey. Support systems, such as group meetings or face-to-face sessions, along with identifying daily lifestyle barriers must be addressed (Garvey et al., 2016).

In addition to lifestyle therapy, pharmacotherapy can be considered in those who are overweight or obese specifically those with weight-related complications that can be improved by weight loss (Garvey et al., 2016). It is important to note the recommended AACE/ACE CPGs (2016) state, "pharmacotherapy for overweight and obesity should be used only as an adjunct to lifestyle therapy and not alone" (p. 36). For optimal weight-loss, clinicians need to consider patient specific medications considering efficacy, side effects, contraindications, medical history, and presence of weight-related complications (Garvey et al., 2016).

For individuals that have failed or have contraindications for pharmacotherapy, bariatric surgery may be an effective obesity treatment. Patients with BMI $\geq$40 kg/m^2 without coexisting

medical problems, patients with BMI ≥35 kg/m^2 with one or more severe obesity-related complication (T2DM, hypertension, NASH, etc...), or patients with BMI of 30 to 34.9 kg/m^2 with diabetes or metabolic syndrome may be considered for a bariatric surgery procedure (Garvey et al., 2016). Surgery is not without risks nor without significant lifestyle changes.

Despite knowledge of diet and exercise, pharmacotherapy, and the advent of new technology (wearable fitness devices and wellness apps), obesity rates continue to escalate. Short-term treatment (3-6 months) with weight-loss medications has not been proven effective in producing long-term health benefits, so maintenance of weight loss is imperative but remains challenging (Garvey et al., 2016). Even weight loss surgery has not been met with a complete reversal of obesity. In those who have had surgery, not following the recommended diet can lead to weight gain not weight loss. Without adequate motivation, solutions will be hard to implement (Emmett & Chandra, 2015).

Theory

The motivation to lose and maintain weight loss requires dedicated strategies. A psychological theory of motivation, the Self-Determination Theory (SDT), along with coaching techniques can help overweight and obese individuals as they adopt healthy lifestyle habits and increase physical activity (Clarke, 2017). The main idea of SDT centers around three basic needs that promote motivation: autonomy, competence, and relatedness (Clarke, 2017, see table 5).

Table 5.

Self-Determination Theory, basic needs

Basic need that promotes motivation	**Definition**	**Definition related to weight-loss**	**Example**
Autonomy	-When one acts on his/her own terms	-Exploring one's own perspectives on behaviors related to physical activity or weight loss interventions	-If an individual physically cannot run or does not like to run, it is important that this is acknowledged and other alternatives for activities are explored
Competence	-When one feels confident they have the ability and resources to achieve a goal	-Optimism, positivity, and providing positive feedback suggest one's ability for successfully adopting and performing new behaviors	-A lapse in behavior, such as failure to exercise, should be considered a temporary setback on the road to success
Relatedness	-Having substantial and supportive relationships (family, friends, healthcare providers, coaches/trainers)	-Occurs with a support system, meeting new people and groups, and networking	-A support group such as weight-watchers that helps attain goals.

Note: data adapted from multiple sources (Clarke, 2017; Patrick & Williams, 2012).

Through autonomy (supporting and recognizing an individual's lifestyle) this gives the individual an opportunity to express perspectives and concerns thus strengthening commitment and accountability for desired behavior change (Patrick & Williams, 2012). By using skills such as problem solving and contingency planning, competence is enhanced, and the individual can effectively learn to cope with challenges, avoid setbacks, and continue his/her ongoing success

(Nag & Durand, 2016; Patrick & Williams, 2012). Relatedness is reaching a goal with the help of a support system. This is important in the sustainability of behavior change.

According to a systematic literature review completed by Teixeira et al. (2012), the most important skill correlated with successful weight loss outcomes was the use of self-regulation. Self-regulation includes monitoring weight and food choices, goal setting and planning (Teixeira, Carraca, Markland, Silva, & Ryan, 2012). Based on the CPGs, after education, motivation, and attempting lifestyle/behavior change, pharmacologic options should be incorporated.

Pharmacologic Weight Management

History of Weight Loss Medications

Medications for weight management has been associated with significant negative effects and perhaps it is this history that impedes providers from exploring the newer drugs. The first weight loss medications were introduced in the 1900s. These anti-obesity medications involved increasing basal metabolic rates (BMR) (Adan, 2013). Thyroid hormones and Tenuate (dinitrophenol) were the first prescription drugs for weight loss, but the increase in BMR caused overheating and death (Adan, 2013).

Later, amphetamines, introduced in the 1930s, looked promising for weight loss but were found to be addictive and produced cardiovascular side effects (Adan, 2013). However, in 1992, fenfluramine was combined with phentermine (Fen-phen) and gained international attention with efficacy of up to 10% bodyweight (Adan, 2013). Unfortunately, this medication combo was discontinued after notable causes of pulmonary hypertension (Adan, 2013). In 1997, the FDA approved sibutramine, but due to cardiovascular changes leading to cardiovascular events (stroke and myocardial infarction) the medication was discontinued (Adan, 2013).

Subsequently, in 1997 Orlistat was introduced; however, side effects such as fecal incontinence and oily stools led to poor compliance (Adan, 2013). Excitingly, in 2012, Qsymia (phentermine plus topiramate) and Contrave (bupropion plus naltrexone), both polytherapies, and Belviq (lorcaserin) were added to the FDA approval list and show great promise for obesity treatment (Adan, 2013). Saxenda (the newest medication) received approval in 2014 and has supportive long-term data for meaningful weight loss, shows great efficacy, but is cost constraining (Velazquez & Apovian, 2018).

Current Prescribing Practices

Nationally, obesity is a chronic disease that affects over 78 million adults, yet only 2% of all eligible obese adults receive pharmacotherapy from a provider (Mehta et al., 2012; Velazquez & Apovian, 2018). According to a Medscape survey of 1282 healthcare providers, only 58% prescribed weight loss medications to those who were overweight/obese (Garvey & Wiebe, 2018). Currently in the U.S. there are eight Food and Drug Administration (FDA)-approved drugs used to help aid in weight loss (Velazquez & Apovian, 2018).

Each medication impacts the body in different ways. Pharmacologic interventions include those that act centrally as noradrenergic agents, medications that interfere with fat absorption, and an analog of human glucagon-like peptide-1 (GLP-1) which suppresses appetite. Three of the most common medications within these categories, Adipex, Contrave, and Saxenda, were evaluated in their efficacy for weight loss.

In 1959, Adipex (phentermine), another amphetamine, was introduced (Adan, 2013). Adipex remains the most commonly prescribed and well researched today due to affordability and limited side effects (Adan, 2013; Velazquez & Apovian, 2018). Adipex (phentermine),

Tenuate (diethylpropion), Bontril (phendimetrazine), and Didrex (benzphetamine), act as appetite suppressants by affecting the central nervous system (Yanovski & Yanovski, 2014).

Adipex (phentermine) is indicated for those with a BMI of ≥30 kg/m^2 or BMI ≥27 kg/m^2 with comorbidities (Phentermine (Rx), 2016). In the United States, an estimated 25.3 million prescriptions were dispensed between 2008-2011 (Velazquez & Apovian, 2018; Yanovski & Yanovski, 2014). This very affordable medication has been proven to result in clinically significant weight loss in a short time (12 weeks) with adjunctive lifestyle modification (Velazquez & Apovian, 2018).

Between 2008-2011, according to the National Institute of Health public access, patients using 15-30 mg/d Adipex had a mean total weight loss of 6.3 kg based on a meta-analysis of six studies over 2 to 24 weeks (Yanovski & Yanovski, 2014). Combination therapy with low doses of Adipex have been approved for long-term obesity management. While Adipex alone has been prescribed long term without evidence of serious side effects and low levels of potential addiction, long-term studies are lacking on monotherapy effects and cardiovascular risk; hence, more long-term studies are needed (Yanovski & Yanovski, 2014).

Orlistat, a gastrointestinal lipase inhibitor, defers fat absorption by blocking some of the fat you eat (Yanovski & Yanovski, 2014). The side effect profile is unpalatable which has decreased its favorability among patients. A version of Orlistat was reformulated to be over the counter (Alli) which unfortunately did not improve its acceptability (Yanovski & Yanovski, 2014).

Belviq (Lorcaserin), a serotonin receptor activator, works as an appetite suppressant by affecting chemical signals in the brain that control appetite (Yanovski & Yanovski, 2014). Two combination medications, Qsymia (phentermine plus topiramate-ER) and Contrave (naltrexone

plus bupropion-SR), work together to suppress appetite (Yanovski & Yanovski, 2014). Regarding Qsymia, phentermine is a noradrenergic agonist, and topiramate ER acts on GABA receptors leading to appetite suppression (Velazquez & Apovian, 2018). For Contrave, the mechanism of action for buproprion SR is the inhibition of dopamine and norepinephrine reuptake; naltrexone acts to antagonize the feedback loop that limits buproprion's anorexic effects, thus the drugs work together to produce appetite suppression (Velazquez & Apovian, 2018). Interestingly, Contrave is a combination of naltrexone and bupropion; naltrexone is approved to treat alcohol and opioid dependence and bupropion is approved to treat depression and seasonal affective disorder and as an aid to smoking cessation treatment (FDA, 2014).

The FDA approved Contrave for long-term use in adults with a BMI of $\geq$30 kg/m^2 or adults with a BMI $\geq$27 kg/m^2 who have at least one weight-related condition such as high blood pressure, type 2 diabetes, or high cholesterol (FDA, 2014). The effectiveness of Contrave was evaluated in multiple clinical trials. In one trial, 42% of patients treated with Contrave lost at least 5% of their body weight compared with 17% of patients treated with placebo (FDA, 2014).

Approved in 2014 by the FDA, Saxenda (liraglutide), a GLP-1 receptor agonist, is the only long-acting daily injectable therapy approved for medical weight loss (Curry, 2017; Isaacs et al., 2016). Saxenda (liraglutide) is the newest weight loss medication on the market and is an analog of human glucagon-like peptide-1 (GLP-1) (Velazquez & Apovian, 2018). Saxenda mimics the endogenous GLP-1 hormone (Velazquez & Apovian, 2018). This hormone is released from the small intestines producing appetite suppression and increases the release of insulin from the pancreas when glucose is present (Velazquez & Apovian, 2018).

Interestingly, recent research has shown medications used for glycemic control in those with type 2 diabetes (T2DM), known as GLP-1 receptor agonists, have produced weight loss

effects in patients with or without diabetes (Isaacs, Prasad-Reddy, & Srivastava, 2016). Saxenda has proven to be effective in moderate weight loss. It has been shown to decrease systolic blood pressure and reduce lipid parameters with minimal side effects including gastrointestinal symptoms such as nausea, vomiting, and diarrhea (Abramowicz et al., 2016; Curry, 2017; Scott, 2015).

A one-year study showed an average of 5.6% decrease in total body weight in those treated with Saxenda (Garvey et al., 2016). One well-designed 56-week phase III trial showed Saxenda was associated with significant ($p < .0001$) waist circumference and BMI reductions from baseline to 56 weeks (Bode et al., 2014). Waist circumference was reduced by 4.7 cm in the Saxenda group compared to 1.2 cm in the placebo group (Bode et al., 2014). Unfortunately, this is the most expensive antiobesity medication on the market at approximately $1100 per month (Curry, 2017).

Cost of Medication

The Affordable Care Act (ACA) covers obesity screenings and counseling (Wilson, Kyle, Nadglowski, & Stanford, 2017). However, obesity treatments, such as medical weight management programs and medications, are not considered essential benefits and many states provide minimal or no coverage for these treatments (Wilson et al., 2017; Yang & Pomeranz, 2015). One study, among 136 marketplace health insurance plans, showed merely 11% had some coverage for drugs (such as Adipex, Contrave, and Saxenda) in only 9 states (Gomez & Stanford, 2018). Medicare policy strictly excludes drug therapy for obesity treatment, and only seven states have Medicaid drug coverage for antiobesity medications (Gomez & Stanford, 2018). Ironically, federal government employees (consisting of roughly 2.7 million

beneficiaries) have health benefit plans that are not allowed to exclude coverage of antiobesity medications (Gomez & Stanford, 2018).

Another study found that obese patients stay on medication longer, see his/her PCP more often, and lose more weight with adequate medication reimbursement (Baum et al., 2015). With the proven clinical effects of pharmacologic obesity management and reducing weight-related complications, this information indicates a need for broader coverage of pharmacotherapy (Gomez & Stanford, 2018). Each FDA approved medication included in this study is listed below along with the mechanism of action, side effects, and overall cost (see table 6). Clearly, one can see that Adipex is the most cost effective.

Table 6.

Medication Overview

Drug/dose	**Mechanism of action**	**Side effects**	**Contraindications**	**Cost/month (some not covered by insurance plans)**	**Efficacy in % of body weight**	**Δ waist circumference**
Adipex (phentermine) 15-37.5 mg oral	Nonadrenalin releaser, appetite suppressant	Insomnia, elevation in heart rate, dry mouth, taste alterations, dizziness, tremors, headache, diarrhea, constipation, vomiting, gastrointestinal distress, anxiety, and restlessness	Not for patients with advanced cardiovascular disease, moderate to severe hypertension, hyperthyroidism, glaucoma, and agitate states	$6-45	-5-10%	-3-4.5 inches

Contrave (bupropion with naltrexone) 8 mg/90 mg oral	Noradrenalin /dopamine reuptake inhibitor and opioid receptor antagonist	Cardiovascular side effects (monitor for increase heart rate and blood pressure), nausea, vomiting, diarrhea, headache, dizziness, insomnia	Not for patients with uncontrolled hypertension, chronic opioid use, seizure disorder, anorexia or bulimia, during withdrawal from alcohol, barbituates, benzodiazepines, and antiepileptic drugs	$90-255	-5-10%	-2-4 inches
Liraglutide (Saxenda) 3mg SQ	GLP-1 receptor agonist at satiety center of brain, resulting in slowed gastric emptying	Nausea, vomiting, gastrointestinal symptoms, possible hypoglycemia, abdominal pain, headache, fatigue, increased lipase Potential serious toxicities: pancreatitis, medullary thyroid carcinoma	Not for patients with personal or family history of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome type 2. Should not be used with insulin or other GLP-1 agonists.	$1,150	Loss of 3.6-5 kgs	4.7 cm
**All antiobesity drugs are contraindicated in pregnancy.						

Note: Data adapted from multiple sources, (Adan, 2013; Fujioka & Braverman-Panza, 2016; Gadde et al., 2018; Goodrx, 2017; Isaacs et al., 2016; Scott, 2015; Yanovski & Yanovski, 2014).

Although lifestyle/behavioral interventions are primary in management, most overweight or obese individuals require adjunctive pharmacotherapy to achieve clinically significant weight

loss (≥ 5% bodyweight reduction) (Scott, 2015). The initial weight loss goal with behavioral changes and pharmacotherapy is 5% or more of total body weight (Velazquez & Apovian, 2018). This weight loss has proven sufficient in reduction of health risks such as hypertension, T2DM, and hyperlipidemia (Velazquez & Apovian, 2018). According to Velazquez and Apovian (2018), "the objective for using pharmacotherapy to manage obesity is to amplify patient adherence to lifestyle changes and to overcome the biological adaptations that occur with weight loss" (p. 107). The quality improvement project proposed in this paper will evaluate the impact of medications Adipex, Adipex plus Contrave, and Adipex plus Saxenda and their effectiveness on BMI, weight loss, and waist circumference.

Purpose

Project Aims

AIM 1: To determine the effectiveness of Adipex on BMI, weight loss, and waist circumference in patients at a rural weight loss clinic.

1. Was BMI, weight, and waist circumference effected in Adipex patients?
2. Did Adipex have barriers (side effects) that prevented medication adherence?

AIM 2: To determine the effectiveness of Adipex plus Contrave on BMI, weight loss, and waist circumference in patients at a rural weight loss clinic.

1. Was BMI, weight, and waist circumference effected in Adipex plus Contrave patients?
2. Did Adipex plus Contrave have barriers (side effects) that prevented medication adherence?

AIM 3: To determine the effectiveness of Adipex plus Saxenda on BMI, weight loss, and waist circumference in patients at a rural weight loss clinic.

1. Was BMI, weight, and waist circumference effected in Adipex plus Saxenda patients?

2. Did Adipex plus Saxenda have barriers (side effects) that prevented medication adherence?

Objectives:

A. Examine a group of 30-100 patients at a rural weight loss clinic taking weight loss medications from September 2014- September 2017.
    a. Each patient was followed for an initial visit, 2-month visit, 3-month visit, and 6-month visit.
        i. Visit 1- Gather baseline data and medication were prescribed
            1. Initial measurements (BMI, weight, waist circumference)
            2. Demographic information, co-morbidities, smoking and alcohol use
            3. Diet and exercise plan
        ii. 2-month visit
            1. Measurements (BMI, weight, waist circumference)
            2. Counseling on diet and exercise adherence
            3. Side effect discussion
        iii. 3-month visit
            1. Measurements (BMI, weight, waist circumference)
            2. Counseling on diet and exercise adherence
            3. Side effect discussion
        iv. 6-month visit, has patient experienced decreased BMI, weight loss, or waist circumference?
            1. Measurements (BMI, weight, waist circumference)

2. Counseling on diet and exercise adherence
3. Side effect discussion

B. Was there any change in metabolic profile between visits?

a. Changes in measurements (BMI, weight, waist circumference)

Methods

This project was a single-center retrospective study of the comparison of three different groups taking Adipex, Adipex plus Contrave, and Apidex plus Saxenda and the effect on weight loss, BMI, and waist circumference. This project also compared the medications on comorbidities and demographics. The sample consisted of 84 patients from a rural weight loss clinic evaluated from September 2014 to September 2017.

Setting

The rural weight loss clinic is a group that specializes in weight loss evaluation, treatment, and management. The clinic is owned by a Family Nurse Practitioner who is the primary provider in the clinic. Improving the overall health of individuals that struggle with being overweight and obese is accomplished within this clinic by educating, assessing, encouraging, motivating, and providing supportive therapy. The rural weight loss clinic provides a medically-supervised weight loss program for people who would like to improve their health by losing weight. The nurse practitioner uses the dual approach of lifestyle modification and anti-obesity medications.

The clinic has been open since 2010. The provider has not completed a thorough assessment of their weight loss outcomes and has requested a chart review. In this setting, the effectiveness of weight loss medications in the treatment of obesity has not been documented. This project was focused on reviewing patient data who have been prescribed Adipex, Adipex

plus Contrave, and Adipex plus Saxenda, and compared the effectiveness of each. Evaluation of effectiveness was based on Body mass index kg/m^2 (BMI), weight in pounds (lbs), and waist circumference (inches).

Sample

For this project, three different groups were evaluated. All selected participants were rural weight loss clinic patients. The review was conducted between September 2014-September 2017. The groups consisted of 34 patients that have taken Adipex, 30 patients that have taken Adipex plus Contrave, and 20 patients that have taken Adipex plus Saxenda to lose weight.

Inclusion Criteria. Rural weight loss clinic patients only with a BMI of $\geq$ 27 kg/m^2 (overweight) with comorbidities present or a BMI of $\geq$ 30 kg/m^2 (obese) with or without comorbidities present (such as hypertension, dyslipidemia, type 2 diabetes). All patients were over the age of 18 and prescribed a weight loss medication. Adherence to a diet and exercise regimen was required. The regimen was not prescriptive and could include participation in group weight loss programs (i.e. Jenny Craig or Weight Watchers).

Exclusion Criteria. Patients who missed a scheduled monthly appointment or patients who had to change medication during course of treatment.

Measurements

The following measures were extracted from the paper patient documented medical records to provide an analysis for objectives (see table 7).

1. Body Mass Index kg/m^2 (BMI), weight (lbs), and waist circumference (inches): BMI, weight in pounds, and waist circumference in inches before and after treatment was gathered to determine weight loss therapy effectiveness.

2. Medication reconciliation document: The medication reconciliation document was used to determine which patients were prescribed Adipex, Adipex plus Contrave, and Adipex plus Saxenda.
3. Metabolic data: An initial assessment was conducted for each patient to identify vital signs and co-morbidities.
4. Demographic data: Demographic data included gender (male vs. female), age (in years), ethnicity, and lifestyle habits (diet, exercise, smoking, ETOH).

Table 7.

Study Measures

Outcome	**Measures**	**Level of Measure**	**Time of Measure**	**Data Collection**
Demographic				
Gender	Male vs female	Nominal	Frequencies, chi-square	Medical records
Ethnicity	White, black, Hispanic, Indian, native American, middle eastern, mixed race, Asian, other	Nominal	Frequencies, chi-square	Medical records
Age	Age in years	Interval/Ratio	Frequencies, chi-square	Medical records
Program Information				
Medical Reconciliation document	Names of medications prescribed to patient	Nominal	Frequencies, chi-square	Medical records
Vital signs (BP, HR)	Blood Pressure-mmHg Heart rate-beats/min	Interval/Ratio	Means (SD), t-test	Medical records
Co-morbidities	Patient documented history	Nominal	Frequencies, chi-square	Medical records

Lifestyle habits (diet, exercise, smoking, ETOH, drug use)	Patient documented history	Nominal	Frequencies, chi-square	Medical records
BMI	kg/m^2	Interval/Ratio	Means (SD), one-way ANOVA	Medical records
Weight	Pounds (lbs)	Interval/Ration	Means (SD), t-test	Medical records
Waist Circumference	Inches	Interval/Ration	Means (SD), t-test	Medical records
Side effects	Patient records	Nominal	Frequencies, chi-square	Medical records

Data Collection

Approvals from the University of Kentucky Institutional Review Board (IRB) were obtained prior to data collection. This project was based on a retrospective chart review. Data collection was completed at the rural weight loss clinic. The clinic used paper documentation and each patient file was selected based on inclusion and exclusion parameters. Data collected was based on the table above including gender, ethnicity, age, medications, vital signs, co-morbidities, lifestyle habits, BMI, weight, waist circumference, and side effects. After data was collected from patient records, using no patient identifiers, data was transferred to an excel spreadsheet.

Data Analysis

Descriptive statistics such as mean and standard deviation or frequency distributions were used to summarize demographic data, medications, vitals, co-morbidities, lifestyle habits, and side effects. The chi-squared test of association (or Fisher's exact test, as appropriate) or the two-sampled t-test was used to test for group differences in demographic characteristics. One-way ANOVA tests were used to test for group differences in change in BMI, weight, and waist circumference (from baseline to each follow up appointment). A post-hoc analysis directed any

significant findings for ANOVA to test which group means differed. All data analysis was conducted using SPSS version 24 with an alpha level of .05.

Results

Sample Characteristics

A total of 250 patient charts were reviewed and 84 were selected based on the inclusion criteria for the retrospective analysis. Of these 84 selected, 34 patients had taken Adipex, 30 had taken Adipex + Contrave, and 20 had taken Adipex + Saxenda. Each patient had taken medication over a 6-month period with visits at baseline, 2-months, 3-months, and 6-months.

The baseline characteristics of these patients were individually assessed. The average age of participants was 45 years of age (range, 19-67 years of age, see table 1); 87% of participants were female. The overall analysis consisted of 99% Caucasian participants and 1% African American participants. The mean BMI of patients at baseline was 36 kg/m^2 (range, 25-54 kg/m^2), average weight at baseline was 218 lbs (range, 144-358 lbs), and average waist circumference at baseline was 40.6 inches (range, 30-60 inches). There were no differences in baseline demographics or baseline physical characteristics between the three groups which demonstrated an even starting point.

Overall comorbidities were assessed with majority consisting of hypertension (37%), prediabetes or diabetes (20%), and GERD (10%). Seventeen percent (17%) reported a family history of heart disease, 7% family history of diabetes, and 4% family history of cancer. Overall lifestyle habits examined alcohol use and smoking with average of 15% of patients consuming alcohol socially and 5% current smokers.

Compliance of a diet and exercise regimen was assessed for each group at each visit. Those taking Adipex had 12% (n=4) noncompliance with a diet and exercise regimen; only half

of those noncompliant still lost weight. Adipex + Contrave users were found to have a 23% (n=7) noncompliance rate with diet and exercise; of those, 86% (n=6) still experienced weight loss. Patients taking Adipex + Saxenda had a 15% (n=3) noncompliance rate with diet and exercise; all still experienced weight loss.

Side effects for each group were evaluated. Twenty nine percent (n=10) of Adipex users reported side effects consisting of GERD, edema, headaches, fatigue, hair loss, constipation, or back pain. Of those 29%, less than one percent (n=2) claimed these undesirable side effects made them noncompliant with medication adherence. Those noncompliant with medications were also noncompliant with diet and exercise. None experienced positive changes in weight loss, BMI, or waist circumference when they did not adhere to the medication or a diet and exercise regimen.

The other groups had combined prescribed medications. The Adipex + Contrave group reported 15% (n=5) experienced side effects such as diarrhea, constipation, and fatigue. This group had a 10% (n=3) noncompliance with medication regimen. Side effects were not a factor in medication adherence for this group. Those that did not take medication as prescribed still adhered to a diet and exercise regimen and experienced a reduction in weight, BMI, and waist circumference.

Adipex + Saxenda users reported 17% (n=5) that experienced side effects such as fatigue, dizziness, constipation, or diarrhea. Of those with side effects, 10% (n= 2) were noncompliant with medication adherence. These patients did not maintain a diet and exercise regimen, but still experienced reduction in BMI, weight, and waist circumference, although minimal.

Overall, 32% of patients reported using a weight loss app on his/her smartphone, 63% reported following a low calorie, high protein diet, and 89% reported some form of

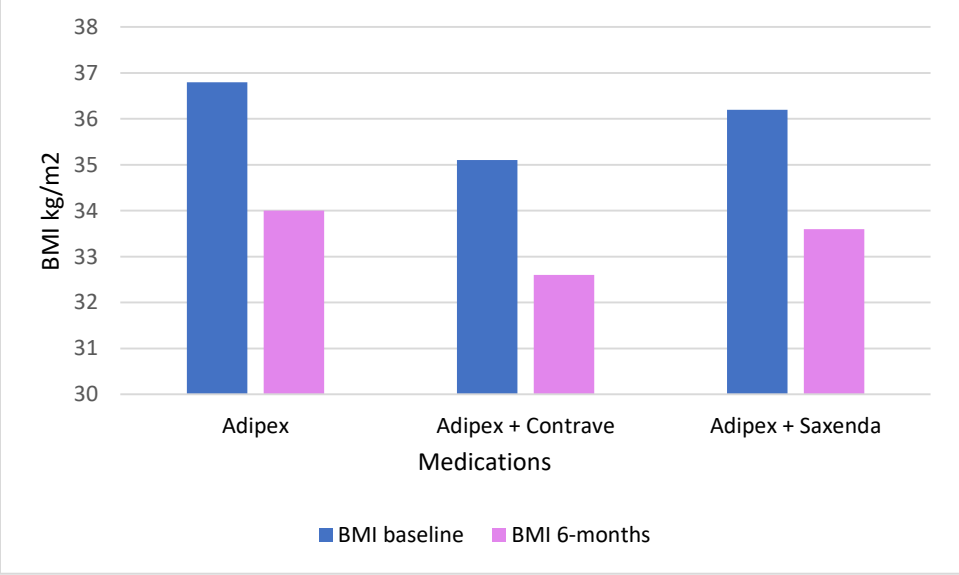
cardiovascular exercise at least twice a week. Overall mean baseline vital signs were 113 systolic and 74 diastolic (mmHg), 88 heart rate, 17 respiratory rate (breaths/min), 96.7º temperature (ºFahrenheit), and 98% oxygen saturation (room air). No significant vital sign changes or outliers were noted throughout the project.

Findings

Intragroup Data

BMI. Individual assessment of BMI for each group was evaluated using a paired t-test (see figure 1). Adipex users experienced an average of 2.7 kg/m^2 reduction in BMI (p= .000). Adipex + Contrave patients had a mean 2.5 kg/m^2 reduction in BMI (p=.000). The Adipex + Saxenda group resulted in an average loss of 2.7 kg/m^2 in BMI (p= .001). Each group had a statistically significant reduction in BMI.

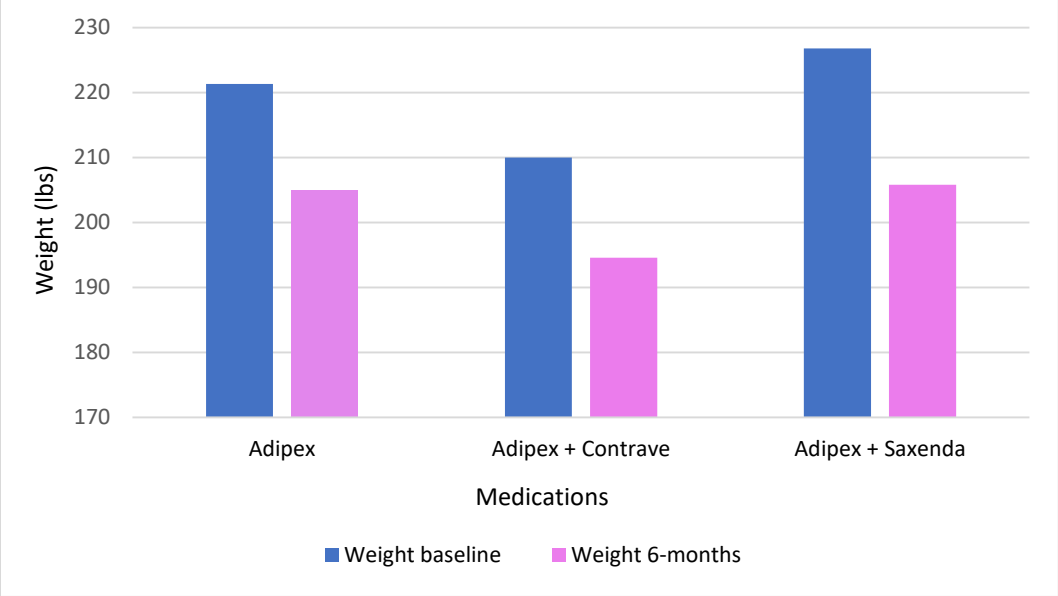
Figure 1. *BMI Loss per Individual Medication*



Note: Each group had a statistically significant BMI reduction.

Weight. Comparing individual drugs and the effect on weight was conducted using a paired t-test (see figure 2). Adipex users experienced an average of 16.3 pounds lost (p= .000). Adipex + Contrave patients had a weight loss of 15 pounds (p=.000). The Adipex + Saxenda group resulted in an average loss of 21 pounds (p= .000). Each group had a statistically significant reduction in weight.

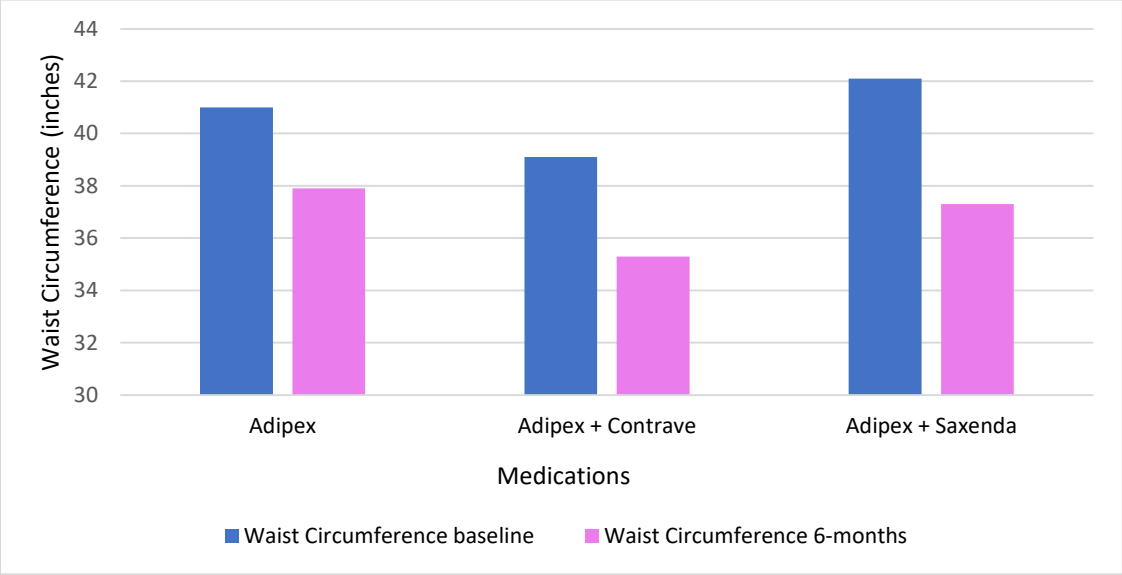
Figure 2. *Weight Loss per Individual Medication*



Note: Each group had a statistically significant weight loss.

Waist Circumference. Individual comparison of each drug and the effect on waist circumference was conducted using a paired t-test (see figure 3). Adipex users experienced a mean of 3.1 inches lost (p= .000). Adipex + Contrave patients had a waist circumference loss of 3.8 inches (p=.000). The Adipex + Saxenda group resulted in an average loss of 4.8 inches (p= .000). Each group had a statistically significant reduction in weight.

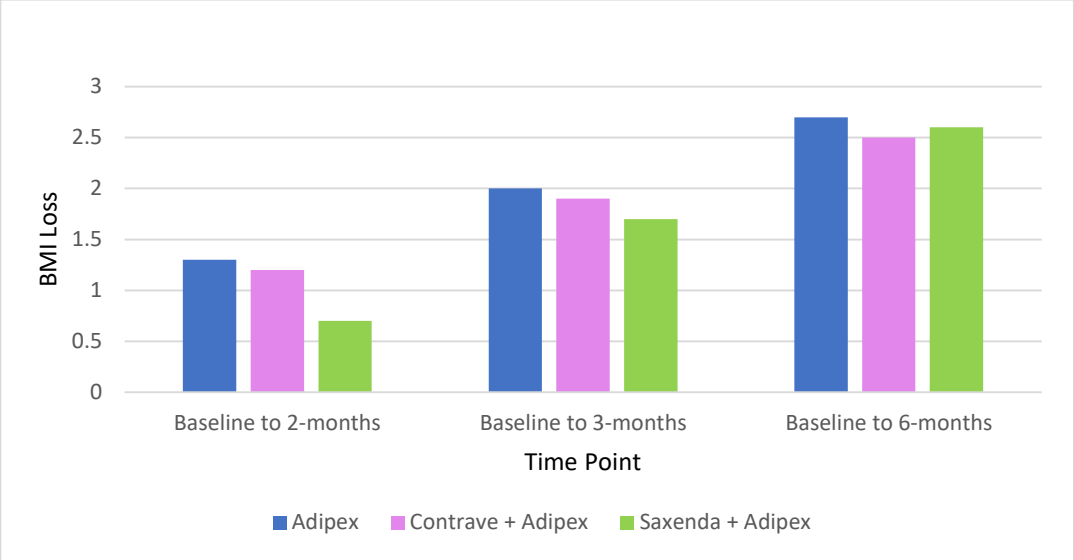
Figure 3. *Waist Circumference Loss per Individual Medication*



Note: Each group had a statistically significant loss in waist circumference.

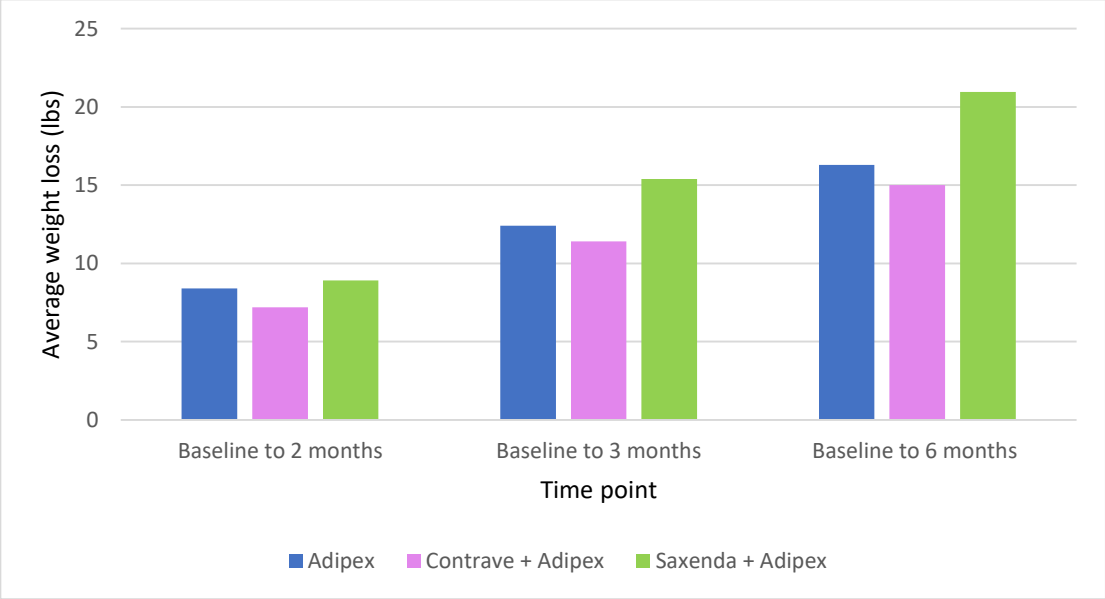
Intergroup Comparison. A one-way ANOVA performed between the three groups for comparison showed no statistical significance in baseline data on age, weight, BMI, and waist circumference. Using a one-way ANOVA, the three groups were compared to note differences in weight, BMI, and waist circumference from baseline to 2-months, baseline to 3-months, and baseline to 6 months. No statistical difference was found in BMI (base – 2 mo, p=.506; base – 3 mo, p=.853; base – 6 mo, p=.961; see figure 4) or weight (base – 2 mo, p=.681; base – 3 mo, p=.451; base – 6 mo, p=.314; see figure 5). The one-way ANOVA comparing the three groups in change in waist circumference from baseline to 3 months was significant (p=.027; see figure 6). In the post hoc analysis, Adipex + Saxenda users had a significantly higher waist circumference difference compared to Adipex (p=.01) and Adipex + Contrave users (p=.03).

Figure 4. *Average BMI Loss Comparing Groups*



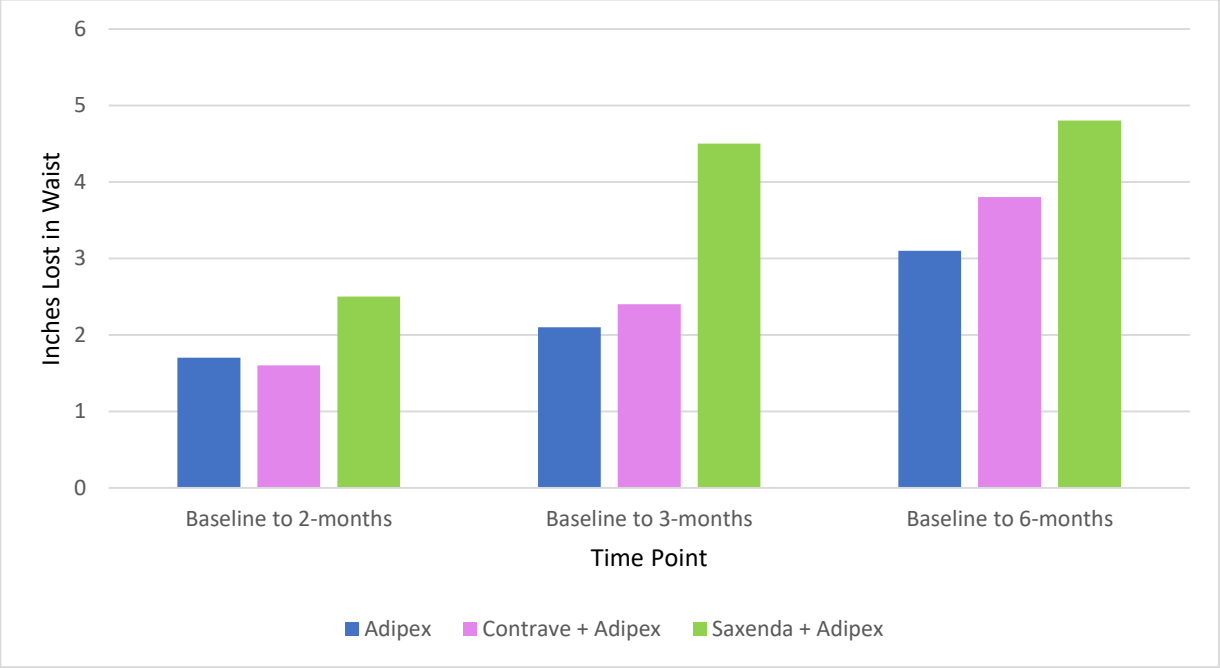
Note: there were no statistical differences in BMI loss between groups.

Figure 5. *Average Weight Loss Comparing Groups*



Note: there was no statistical difference in weight loss between groups.

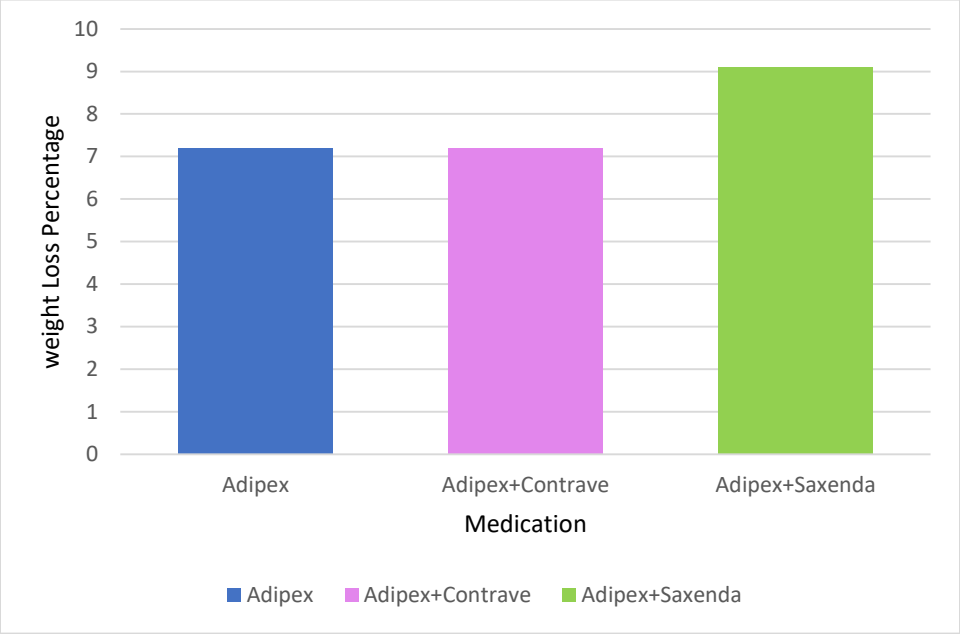
Figure 6. *Average Waist Circumference Loss Comparing Groups*



Note: Statistical significance was noted from baseline to 3-months in waist circumference loss.

Between the three groups, there was no statistical significance in the percentage of weight loss. On average, all groups experienced clinically significant weight loss (>5% total weight loss percentage). Patients taking Adipex experienced 7.2% weight loss percentage (range, -3.5 to 16%, see figure 7). Patients taking Adipex + Contrave also averaged a weight loss percentage of 7.2% (range, -7.5 to 16%). Those taking Adipex + Saxenda averaged the most weight loss percentage of 9.1% (range, 2 to 22%).

Figure 7. *Average Weight Loss Percentage over 6 months*



Note: there was no statistical difference in weight loss percentage between groups.

Discussion

The growing emphasis placed on weight loss has spurred the opening of dedicated clinics to assist people with their weight loss journey. Evaluating results in patients who attend such a clinic must be viewed under the lens of self-selection. These patients elect to seek out treatment outside of just diet and exercise. Many providers in the primary care setting only decide to initiate weight loss medications after a patient has trialed a recommended diet and exercise plan (Garvey & Wiebe, 2018). While patients may be trialing diet and exercise regimens, many become discouraged by lack of fast weight loss and seek pharmacotherapy at weight loss clinics (Heymsfield & Wadden, 2017).

Demographics

Nationally, in 2014, those between the age of 40-59 years were more likely to be obese (41%) thus correlating with the average age in this study of 45 years (State of Obesity, 2017). Ethnically, this project was not diverse. According to studies, African American women report taking pride and having a positive body image, while white women expressed self-depreciation and depression (Chugh, Friedman, Clemow, & Ferrante, 2013). This information concurred with the data of primarily white females for this project.

Age, gender, and race were not evaluated between groups for the effectiveness of medications due to the small and unvaried sample size. In completing the review of literature, no evidence was noted that there is a difference between ethnicities, gender, or age and the effectiveness of weight loss medications. Though, socioeconomic status was not addressed in this project, it would have offered insight to the burden of cost on taking prescription weight loss medications. Of note, many of the patients evaluated in this project did have insurance coverage. Whether the insurance covered the medications prescribed could not be determined.

Medications

According to literature, numerous studies have shown greater weight loss outcomes with combination therapy as opposed to monotherapy (Velasquez & Apovian, 2018). This retrospective analysis did not statistically support those findings. However, this could be due to the small sample size, noncompliance, or lack of proper medication choice for the patient as everybody responds differently.

Adipex. Per discussion with the provider of the weight loss clinic, patients often present requesting Adipex. They have heard of its effectiveness and affordability. Adipex is the cheapest weight loss medication available with minimal side effects (Adan, 2013). While the side effect

profile was largest for this group (29%), side effects were not serious and did not lead to significant medication noncompliance. For over two decades, this medication has been prescribed in the U.S. without serious side effects and low addiction potential (Velasquez & Apovian, 2018). Findings in this retrospective analysis support its effectiveness making this medication a feasible first line option for weight loss management.

Adipex + Contrave. Contrave has demonstrated effectiveness when used alone. There was no evidence to support adding Adipex to Contrave. Per comparison with other studies, common side effects such as gastrointestinal upset correlated with the project findings (Velasquez & Apovian, 2018). With no evidence found in this project to suggest Adipex and Contrave had more benefits than Adipex alone, it is the addition side effect profile that must be considered when adding another drug, although only 15% experienced minimal side effects in this project.

Adipex + Saxenda. Adipex + Saxenda demonstrated no added benefit when combined for weight loss. Only 17% experienced minimal side effects, and those noncompliant with diet and exercise still experienced weight loss. Findings of weight loss while using medication only correlates with literature reviews (Velasquez & Apovian, 2018).

A Statistical significant difference in waist circumference was noted between the groups. From baseline to 3-month data point, Adipex + Saxenda users had the greatest reduction. This finding remains curious as there was no real difference in the amount of weight lost between groups. One might surmise that either waist circumference was not measured properly, or body shape could influence area of weight loss. Saxenda is a GLP-1 receptor agonist creating insulin sensitivity and targets adiposity in the abdominal region; which could explain waist reduction (Velazquez & Apovian, 2018). Waist circumference has not been adopted as a standard for evaluating for obesity because of the variability in measurement (Ma et al., 2013).

Comorbidities. The only comorbidity that was evaluated was hypertension. In this sample, there was no evidence of hypertension. At baseline, none were hypertensive (even the ones reporting hypertension in medical history) which could indicate they were already receiving treatment. Given that this clinic was still using paper charts, a complete medication list was not readily found. Laboratory values were not included or assessed to follow improvements in hyperlipidemia, thyroid issues, diabetes, or other comorbidites.

Interestingly, in this analysis there was only 3% depression/anxiety comorbidities reported overall. It was difficult to interpret this finding given the medication list was not complete. Per research findings, psychological symptoms such as anxiety and depression show a bidirectional relationship with obesity (Collins et al, 2016). Given the data, a higher percentage of patients in this analysis were expected to report depression and anxiety as a comorbidity. Sample size and ongoing treatment could have influenced this finding.

Medication Compliance. Medication, diet, and exercise compliance were assessed during this retrospective project. According to the 2018 Medscape study by Garvey and Wiebe, providers preferred the patient to focus on diet, exercise, and behavioral therapy because they were concerned about safety and side effects of mediations. Thirty two percent of those surveyed admitted they did not have enough knowledge about weight loss medications (Garvey & Wiebe, 2018). Results from this project determined side effects were minimal and were not a deterrent for adherence to medication compliance. Therefore, there is a need for provider education on side effects and safety of weight loss medications.

Activities. Diet tracking apps, cardiovascular exercise, and low calorie high protein diets are recommended and expected at the rural weight loss clinic. Each patient is educated on these

aids and is strongly informed that this is a part of the weight loss plan. For good outcomes, none of these three things can be excluded.

Compliance with cardiovascular exercise at 89% was surprising as finding time and motivation to exercise is a barrier (Heymsfeld & Wadden, 2017). Exercise compliance was unexpected due to Kentucky's limited rate in physical activity of 30% (Walsh et al., 2016). It is important to note this is a self-selected group independently seeking weight loss, which indicates readiness for change; therefore, they are more motivated to adopt these lifestyle changes.

Implications

Primary care providers have a great responsibility in obesity education and management. Clinical Practice Guidelines provide vast information on obesity screening and management as well as comorbidity assessments. Evaluation of BMI should be evaluated at least annually for each patient, screening for overweight and obesity, and then treating per guideline recommendations.

Based on the CPGs, PCPs should be addressing and treating overweight individuals as a precursor and work towards preventing the disease of obesity. Similar to hypertension, education and options for diet and exercise should be presented to the patient well before the patient nears the overweight BMI window. The progression to obesity and other comorbidities can be offset with dedicated interventions.

Any environmental characteristic that acts as barrier to healthy body weight is considered obesogenic (Lakerveld, Mackenbach, Rutter, & Brug, 2018). Poor diet and sedentary lifestyle are modifiable factors that are directly linked to our obesogenic environment (Lakerveld et al., 2018). Our surrounding such as availability of food, food traditions, institutional rules (school

food rules), and food prices effect our diet and lifestyle decisions daily (Lakerveld et al., 2018). Ways to avoid these barriers should be addressed with patients.

The difficulties of achieving and maintaining weight loss is a significant challenge where all barriers should be addressed (Puhl et al., 2017). Addressing barriers such as bias, access to care, socioeconomic factors, cost, and lifestyle/behavior should be included in evaluation and planning of overweight and obese patients. With this knowledge, we need to start looking at novel interventions such as telemedicine. Telemedicine, health groups, and trainers should be included in aiding weight loss if possible (Alencar et al., 2017). Mobile phone-based health coaching and weekly video conferencing have been effective in clinically significant weight loss (Alencar et al., 2017). Use of smartphone apps and wearable fitness devices should be encouraged if the individual views it as necessary to aid in weight loss/management.

More importantly, PCPs need to step up and embrace actively helping their patients lose weight. One might wonder why we need dedicated weight loss clinics where diet, exercise, and weight loss medications are sought out. In essence, this can create silos of patient care where coordination of care is impeded and is more costly for this patient. For example, a patient must pay a copay every time he/she goes to the PCP and weight loss clinic. What is it that makes PCPs not address weight loss strategies?

Weight stigmatization affects obese individuals every day and opportunities for improvement in the workplace, schools, healthcare, and media are beginning to be discussed at a federal level (Pearl, 2018). As providers, overcoming weight stigmatization and incorporating the SDT as a model of practice could have positive results on weight management. Helping individuals adopt coping strategies to deal with stigmatization and emotional distress will

advance weight loss management and facilitate opportunities for intervention and improve social identity (Pearl, 2018; Puhl et al., 2017).

Is it possible that weight stigmatization is what drives individuals to a weight loss clinic? They may feel that talking to the PCP and asking for a weight loss medication is a sign of weakness or they will be lectured on diet and exercise compliance. In one study, patients stated they let comorbidities exacerbate to a severe degree before seeking care because they wanted to avoid feeling shamed by their provider (Okwerekwu, 2016). All healthcare providers are encumbered to recognize obesity as a disease and treat as aggressively as they may treat heart disease but approach the issue without bias.

Limitations

Several limitations should be acknowledged. The generalization of the study was limited to data collection only being from one establishment. Due to the rural nature of the clinic, the sample size for this project was small and consisted of a significantly non-diverse population. Statistical difference between groups could have been limited due to small sample size. Paper documentation of patient health records increased the difficulty and time constraint of data collection limiting the number of participants, accuracy of information input, and amount of data collected (lab values, concurrent medications, change in comorbidities, cost per individual). Because this study was retrospective, verification of reported results was not possible. Compliance of diet, exercise, and medication regimen could have skewed results.

Conclusion

Rates of obesity are predicted to rise, with attention to the severely obese subgroup (BMI >40) which is increasing rapidly (Gotthardt & Bello, 2016; Sturm & Hattori, 2013; Velazquez & Apovian, 2018). Although not a cure all, anti-obesity pharmacotherapy serves as a part of the

solution for the obesity epidemic in the U.S. (Gomez & Standford, 2018). It is important to note, pharmacotherapy is an adjunctive therapy to diet and exercise and has not proven significant weight loss without adherence to a diet and exercise plan. Discussion of weight loss medication should be included with every overweight/obese individual that falls in to recommended guidelines. PCPs with time constraints or lack of knowledge about medication should refer patients to weight loss clinics but all providers have to be communicating.

Despite clinically significant weight loss achieved with newer antiobesity drugs such as Saxenda, only a small portion of eligible patients are using them due to high cost (Gadde et al., 2018). Quality driven healthcare initiatives along with Federal and State coverage mandates could make way for change in the coverage of obesity medications (Gomez & Stanford, 2018). In policy, providers are the patient advocate; as providers, staying informed and engaged in health care policy changes is imperative for change.

It took 50 years to publicize the link between tobacco use and lung cancer (Malhotra, 2016). Big Tobacco companies fought regulation, but through taxation and guidelines in advertising, the government substantially declined tobacco consumption over the past three decades (Malhotra, 2016). This was the single most important factor in decreasing cardiovascular mortality during this period. Obesity is the new tobacco and will take a concerted effort to reverse the upward trend.

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