Journal of Pharmacy Technology
2016, Vol. 32(1) 37–41
© The Author(s) 2015
Reprints and permissions:
sagepub.com/journalsPermissions.nav
DOI: 10.1177/8755122515604858
pharmatech.sagepub.com
SAGE

Review of Pharmacologic Weight Loss Medications in a Patient-Centered Medical Home

Tracy Costello, PharmD, BCPS[1], Megan Dorrell, PharmD, BCPS[2], Taryn Kellams, PharmD[3], and Kim Kraska, PharmD[4]

Abstract

Background: Per the Centers for Disease Control, 78 million adults were classified as obese in the United States in 2009 to 2010. Lifestyle modifications and pharmacologic treatment are appropriate options to combat obesity. **Objectives:** The primary objective of the study was to assess change in body weight after 12 weeks in patients seen at a family medicine patient-centered medical home (PCMH) who were prescribed Food and Drug Administration–approved weight loss medications. **Methods:** A retrospective medical record review was used to evaluate weight loss in adult patients with office visits at the PCMH. Adult patients were eligible for inclusion in the study if prescribed a Food and Drug Administration approved weight loss medication between July 1, 2013, and March 31, 2014, and had at least one weight documented during a follow-up visit 12 weeks after the initial prescription. **Results:** Of the 27 patients identified for study inclusion, 22 (81.5%) were prescribed phentermine. The remaining 5 (18.5%) patients were prescribed phentermine/topiramate ER. After 12 weeks of pharmacologic therapy, the median change in body weight was −3.7 kg (range = −16.8 to 5.5 kg) regardless of medication taken. This correlates to a −1.4 kg/m^2 (range = −15.7 to 4.2 kg/m^2) median change in body mass index. Twelve patients (44.4%) lost at least 5% of their body weight during the study period. **Conclusions:** In our study population, we observed a median weight loss of 3.7 kg over 12 weeks while utilizing weight loss medications. Unfortunately, other lifestyle-modification services offered through the PCMH were not consistently utilized.

Keywords

weight loss, phentermine, phentermine/topiramate ER, patient-centered medical home

Background

The American Heart Association/American College of Cardiology/the Obesity Society (AHA/ACC/TOS) Guidelines for Management of overweight and obesity in adults defines overweight as a body mass index (BMI) of 25 to 29.9 kg/m^2 and obese as a BMI ≥ 30 kg/m^2. In 2009, 78 million adults in the United States were classified as obese.[1] Many risks are associated with obesity such as morbidity and mortality from hypertension, dyslipidemia, type 2 diabetes mellitus, coronary heart disease, stroke, gallbladder disease, osteoarthritis, sleep apnea, respiratory problems, and cancer.[1,2] With the overwhelming number of obese adults determined in 2009, it is not surprising that health care costs of obesity total over $140 billion, indicating that proper management of obesity is crucial to minimize costs and the risks mentioned previously.[1]

After assessing the need and readiness of the patient to lose weight, engagement in lifestyle modifications is the standard first step in treatment. Lifestyle modifications producing a weight loss of 3% to 5% are beneficial to overall health in overweight and obese adults. Potential benefits may include clinically meaningful reductions in triglycerides, blood glucose, hemoglobin A1C (HbA1C), and the risk of developing type 2 diabetes mellitus.[1] Examples of lifestyle modifications may include a reduced calorie diet, increased physical activity, and individual or group sessions with a trained interventionist.

The AHA/ACC/TOS guidelines recommend pharmacologic treatment to be added as an adjunct to lifestyle interventions if the patient has not lost 5% of their total weight or if they have not seen the desired progression in weight

[1]Butler University, Indianapolis, IN, USA
[2]Community Health Network, Indianapolis, IN, USA
[3]CVS Health, Indianapolis, IN, USA
[4]Jewel-Osco Pharmacy, Chicago, IL, USA

Corresponding Author:
Tracy Costello, PharmD, BCPS, Butler University College of Pharmacy and Health Sciences, 4600 Sunset Avenue, Indianapolis, IN 46208, USA.
Email: tcostell@butler.edu

loss after 6 months.[1] However, more recently published clinical practice guidelines from an Endocrine Society-appointed Task Force, sponsored by the European Society of Endocrinology and the Obesity Society, support early use of pharmacologic treatment for obesity to improve comorbidities and enhance adherence to behavior changes.[2] Providers should consider pharmacotherapy options that have been Food and Drug Administration (FDA) approved for weight loss.[2] At the time of the study, there were 4 FDA-approved medications for weight loss. These medications work through effects on appetite or fat absorption, which helps promote patient adherence to dietary changes.[1]

Phentermine was FDA-approved in 1959 and is the most commonly prescribed treatment option for obesity; however, its labeling only recommends short-term use, up to 12 weeks.[3] Phentermine is a sympathomimetic amine that reduces appetite by central nervous system stimulation of norepinephrine, serotonin, and dopamine, resembling the mechanism of stimulant medications. According to a meta-analysis of 6 placebo-controlled randomized trials completed from 1975 to 1999, phentermine therapy was correlated with a 3.6 kg greater weight loss compared with placebo during a duration of use of 2 to 24 weeks.[4]

Phentermine/topiramate ER, a combination product, was approved by the FDA in 2012 and is taken once daily in the morning. It was approved for long-term use in combination with lifestyle modifications in obese or overweight individuals. Although the mechanism of action of topiramate for weight loss is generally unknown, it is believed to be beneficial by enhancing the activity of GABA.[5,6] Topiramate is considered to be an efficacious treatment for obesity since low doses can be used and regaining of lost weight is successfully prevented after the medication is stopped. The combination product has a mean percent weight reduction of 8.5% to 9.2% compared to 6.1% with phentermine and 6.4% with topiramate, individually.[6] One study demonstrated patients lost an average of 9.3% to 10.5% while on phentermine/topiramate ER 7.5/46 mg and 15/92 mg doses, respectively.[7]

Orlistat, which is available over the counter or with a prescription, is approved for the treatment of obesity in long-term settings. It is a pancreatic lipase inhibitor that works by reducing the absorption of dietary fat, so it is taken 3 times daily with each main meal.[8] Its effect on weight loss is modest, regaining of lost weight is likely when the medication is stopped, and its gastrointestinal side effects are limiting.[9] A meta-analysis of 22 studies showed Orlistat produced an average 2.89 kg weight loss over 12 months compared to placebo.[10]

Lorcaserin was FDA approved in June 2012 for use in patients with a BMI $\geq$ 30 kg/m^2 or those with a BMI $\geq$ 27 kg/m^2 plus at least one weight-related health condition, such as hypertension, dyslipidemia, or type 2 diabetes mellitus.[11] Lorcaserin decreases food intake and increases satiety by acting within the hypothalamus as a selective serotonin 2C receptor agonist. Lorcaserin's effect is also mediated by release of melanotropin-α, which stimulates melanocortin receptor-4, resulting in appetite satiety.[11] Patients taking lorcaserin doses twice daily and once daily had a mean weight loss of 4.7% and 5.8%, respectively, compared to 2.8% with placebo.[12]

Need for Study

A family medicine patient-centered medical home (PCMH) was selected for the study site. This practice model aims to improve quality, cost, along with patient and provider experience. The PCMH model emphasizes comprehensive, coordinated, accessible care with a focus on safety.[13] The use of a PCMH as the study site and retrospective medical record review allowed for a real-life reflection of weight loss in patients using pharmacologic and nonpharmacologic methods without strict follow-up regimens. In addition, this study population had access to additional weight loss resources, such as a registered dietician and medication counseling by a pharmacist, as a part of the PCMH.

Objectives

The goal of the study was to evaluate the use and outcomes of weight loss medications in a PCMH. The primary objective of the study was change in body weight after 12 weeks in patients at a PCMH who have been prescribed a FDA-approved weight loss medication. Secondary objectives included the proportion of patients losing at least 5% of their baseline body weight after 12 weeks and the proportion of patients with documented lifestyle modification counseling or services offered through the PCMH.

Methods

Study Design and Population

A retrospective medical record review was used to evaluate weight loss associated with the use of pharmacologic treatment. Adult patients with physician appointments between July 1, 2013, and March 31, 2014, at the family medicine PCMH were screened for inclusion in the study. To be eligible for inclusion in the study, patients had to be between 18 and 89 years of age, had their first prescription for a FDA-approved weight loss medication during this time frame, and had a recorded weight resulting from a follow-up visit with any provider after at least 12 weeks of taking the prescribed medication. The follow-up time frame included appointments through June 30, 2014. The medications included at the time of the study were phentermine, phentermine/topiramate ER, lorcaserin, and orlistat. Patients were identified for possible inclusion for the study through an electronic search

of the electronic medical record for prescriptions for the 4 medications within the designated time frame. Patients were excluded if they were pregnant, had documentation of never taking the prescribed weight loss medication, started the medication prior to the study time frame, or if no follow-up information was available.

For primary and secondary endpoints, weight and height at baseline and follow-up visits were collected. BMI, change in weight, and change in BMI were calculated through statistical analysis. Additionally, education on lifestyle modification and PCMH resources offered, such as dietician or pharmacist referral, was included if documented anywhere in the medical record from time of initial visit to 12-week follow-up. A subgroup analysis of results in our patient population related to individual medications was also performed.

Descriptive statistics were used to analyze the data. Statistical analysis was performed using Microsoft Excel. This study was approved by the local institutional review board.

Table 1. Baseline Demographic Data (N = 27).

Age, median (range)	34 years (22-54)
Sex, n = female (% of study population)	25 (92.6%)
Comorbidities, n (% of study population)	Diabetes: 1 (3.7%)
	Hypertension: 5 (18.5%)
	Hyperlipidemia: 4 (14.8%)
	Other: 11 (40.7%)
	Depression: 8
	Anxiety: 2
	Bipolar: 1
Prescribed weight loss medication, n (% of study population)	Phentermine: 22 (81.5%)
	Phentermine/topiramate ER: 5 (18.5%)
Number of additional visits during 12-week study time frame, median (range)	2 (0-6)

Results

Sixty-three patients were identified as eligible for study inclusion based on age and having appointments where prescriptions were written for the assigned medications during the designated time frame. Following further chart review, a total of 27 patients were included in the final analysis. Twenty-two (81.5%) of the included patients were prescribed phentermine. The remaining 5 (18.5%) patients were prescribed phentermine/topiramate ER. The majority of the patients included were female with a median age of 34 years (range = 22-54 years). Table 1 outlines baseline demographics of the study population. Thirty-six patients were excluded from the study due to the weight loss medication being a refill rather than initial start (n = 7), documentation of not filling the prescription (n = 4), not having a follow-up weight available (n = 24), or stopping the study medication due to side effects (n = 1) during the study time frame.

The majority of patients in the study were obese at baseline with a median baseline weight of 113.6 kg and median BMI of 40.7 kg/m^2. After 12 weeks of pharmacologic therapy, the median change in body weight was −3.7 kg regardless of medication taken. This correlates to a −1.4 kg/m^2 median change in BMI. Table 2 summarizes the data surrounding the primary objective.

For the study's secondary objectives, it was noted that 12 patients (44.4%) lost at least 5% of their body weight. Of these patients, 11 were taking phentermine. Twelve (44.4%) of the patients had documentation of lifestyle modification counseling or services offered through the PCMH. The most common lifestyle modification documented was physician education (n = 14) on exercise and dietary changes followed by a dietician referral (n = 7) and encouraged use of a food log (n = 5).

In a subgroup analysis of the individual drugs prescribed to the study population, the median change in weight from baseline was −4.3 kg (range = −13.9 to +5.5 kg) and −2.2 (range = −16.8 to +0.1 kg) for patients taking phentermine and phentermine/topiramate ER, respectively. The median change in BMI for patients taking phentermine was −1.5 kg/m^2 (range = −4.7 to +1.9 m^2) and −1.4 kg/m^2 (range = −7.3 to +0.1 kg/m^2) for patients taking phentermine/topiramate ER. Table 2 shows in detail the differences in weight for both the phentermine and phentermine/topiramate ER groups. No additional statistical analysis was completed comparing the groups due to the small sample size.

Discussion

Obesity has been described as a growing epidemic in the United States, resulting in increased morbidity, mortality, and health care costs.[4] In efforts to combat this growing problem, multiple drug classes have been approved in recent years to help patients achieve desired weight loss; however, there are limited studies that reflect "real-world" prescribing habits and follow-up. Previously published prospective studies offer patients intense lifestyle modifications with frequent follow-up visits.[1,2] This study focuses on the effectiveness of weight loss medications prescribed in a PCMH model; however, because many patients did not use the resources offered by the PCMH, the study is applicable to the general population.

The study was limited due to its retrospective medical record review design and lack of a comparator group. A small sample size resulted from over half of the reviewed

Table 2. Weight and Body Mass Index (BMI) Outcomes.

	Weight		
	All Patients (N = 27)	Phentermine (n = 22)	Phentermine/Topiramate ER (n = 5)
Baseline, median (range)	113.6 kg (75.8 to 156.6)	109.5 kg (75.9 to 156.6)	115.5 kg (75.8 to 134.5)
12-week, median (range)	106.8 kg (74.1 to 142.7)	105.2 kg (74.1 to 142.7)	106.8 kg (75.9 to 132.3)
Change in weight, median (range)	−3.7 kg (−16.8 to 5.5)	−4.2 kg (−13.9 to 5.5)	−2.2 kg (−16.8 to 0.1)
Percent change, median (range)	−4.0% (−15.7% to 4.2%)	−4.9% (−12.3% to 4.2%)	−2.8% (−15.7% to 0.2%)
	BMI		
	All Patients	Phentermine	Phentermine/Topiramate ER
Baseline, median (range)	40.7 kg/m^2 (25.7 to 60.4)	40.7 kg/m^2 (27.2 to 60.4)	46.4 kg/m^2 (25.7 to 51.0)
12-week, median (range)	38.9 kg/m^2 (25.7 to 61.1)	38.5 kg/m^2 (25.7 to 61.1)	40.9 kg/m^2 (25.8 to 49.6)
Change in BMI, median (range)	−1.4 kg/m^2 (−7.3 to 2.0)	−1.5 kg/m^2 (−4.7 to 2.0)	−1.4 kg/m^2 (−7.3 to 0.1)
Percent change, median (range)	−3.7% (−17.9% to 4.2%)	−3.9% (−12.2% to 4.2%)	−2.8% (−17.9% to 0.4%)

patients being excluded from the study due to lack of follow-up. No additional data is available on these patients. In previous weight loss studies, there were limited conclusive data with regard to impact on obesity-related comorbidities such as hypertension, hyperlipidemia, and type 2 diabetes mellitus. The same holds true in this study, as this would be difficult to evaluate with the sample size and only a few patients that met inclusion criteria presented with those specific comorbidities. Due to the short follow-up time period in this review, long-term or sustained weight loss and patient compliance with pharmacologic and lifestyle treatments were not evaluated. This study was also limited by only analyzing patients taking phentermine and phentermine/topiramate ER. Although patients during the study time frame were prescribed lorcaserin or orlistat, none of those patients met inclusion criteria. The dosage of the medications included in the study was not included in data collection, adding to the limitations of the study.

This study demonstrated weight loss results in patients who continued on pharmacologic therapy and returned for a follow-up visit after 12 weeks. The majority of the included patients lost weight with a median weight loss of 3.7 kg (range = −16.8 to 5.5) in the 12-week follow-up period. This is equivalent to a healthy and sustainable weight loss of 1 to 2 pounds per week (0.45-0.9 kg).[1] Unfortunately, not all patients lost weight as evident in the total range of the primary endpoint. Patients reported minimal side effects, with only one patient discontinuing therapy due to an undocumented reaction. Weight loss in the study patients has the potential to be affected by a number of factors including physician education, patient motivation, and lack of resources to maintain healthy lifestyles, which were all hard to capture in the retrospective medical record review design. Education provided to each patient was dependent on time spent with the patient during their appointment, proper referrals to specialists, and amount of follow-up visits. Based on the low number of patients with documented nonpharmacologic interventions, this is an area to focus on with providers to help improve patient outcomes.

Future studies should be pursued to compare efficacy of lifestyle modifications alone or in combination with an FDA-approved weight loss medication in the PCMH model. Medications that became FDA-approved for weight loss after this study period, such as bupropion/naltrexone and liraglutide, should also be subject to future research.

Conclusion

This study demonstrated that patients seen at a PCMH can have successful short-term weight loss with pharmacologic therapy. The study population lost a median of 3.7 kg (range = −16.8 to 5.5 kg) over 12 weeks while taking either phentermine or phentermine/topiramate ER. Of note, after 12 weeks, 44.4% of patients lost at least 5% of their body weight. Unfortunately, not all patients had documentation of lifestyle interventions or counseling. The results of using pharmacologic therapy alone in a PCMH are encouraging according to the data presented. Although not demonstrated in our study, it is important for patients to work closely with their physician along with increased utilization nonpharmacologic interventions in order to achieve their weight loss goals.[2]

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

References

1. Jensen MD, Ryan DH, Apovian CM, et al. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. *J Am Coll Cardiol*. 2014;63:2985-3023.
2. Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological management of obesity: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab*. 2015;100:342-362.
3. Phentermine [Package insert]. Phoenix, AZ: Apotheca, Inc; 2010.
4. Zhaoping L, Maglione M, Wenli T, et al. Meta-analysis: pharmacologic treatment of obesity. *Ann Intern Med*. 2005;142:532-546.
5. Qsymia [Package insert]. Mountain View, CA: Vivus, Inc; 2012.
6. Sweeting AN, Tabet E, Caterson ID, Markovic TP. Management of obesity and cardiometabolic risk—role of phentermine/extended release topiramate. *Diabetes Metab Syndr Obes*. 2014;7:35-44.
7. Garvey TW, Ryan DH, Look M, et al. Two-year sustained weight loss and metabolic benefits with controlled-release phentermine/topiramate in obese and overweight adults (SEQUEL): a randomized, placebo-controlled, phase 3 extension study. *Am J Clin Nutr*. 2012;95:297-308.
8. Orlistat [Package insert]. Nutley, NJ: Roche Laboratories, Inc; 2009.
9. Drew BS, Dixon AF, Dixon JB. Obesity management: update on orlistat. *Vasc Health Risk Manag*. 2007;3:817-821.
10. Hollander PA, Elbein SC, Hirsch IB, et al. Role of orlistat in the treatment of obese patients with type 2 diabetes: a 1-year randomized double-blind study. *Diabetes Care*. 1998;21:1288-1294.
11. Lorcaserin [Package insert]. Zofingen, Switzerland: Arena Pharmaceuticals; 2012.
12. Fidler MC, Sanchez M, Raether B, et al. A one-year randomized trial of lorcaserin for weight loss in obese and overweight adults: the BLOSSOM trial. *J Clin Endocrinol Metab*. 2011;96:3067-3077.
13. Thygeson NM, Peikes D, Zutshi A. *Mixed Methods: Fuzzy Set Qualitative Comparative Analysis and Configurational Comparative Methods: Powerful Methods to Study and Refine Patient-Centered Medical Home Models* (AHRQ Publication No. 13-0026-EF). Rockville, MD: Agency for Healthcare Research and Quality; February 2013.