The Impact of a Clinical Pharmacist in an Interdisciplinary Weight Loss Service: A Follow-Up Study

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Abstract
***Background**: At an Internal Medicine outpatient clinic, patients are referred to a weight loss service by their primary care physician to be managed by a clinical pharmacist and dietician.*
Objective: A study was conducted to determine the impact of this established, interdisciplinary, pharmacist-driven weight loss service on percent weight loss from baseline in patients who are obese or overweight compared to those receiving standard weight loss care.
***Methods**: This was a retrospective, single-center, cohort study including adults ≥18 years of age with BMI ≥30 or BMI ≥27 with at least one weight-related comorbidity such as hypertension, dyslipidemia, or type 2 diabetes mellitus, and referred to the clinic's weight loss service or managed by their primary care physician. The primary outcome was percent weight loss from baseline. Key secondary outcomes included number of patients who had >5% weight loss in 6 months, number of patients who received liraglutide after 6 months, and percent weight loss in patients prescribed liraglutide. Statistical analysis included descriptive statistics, t-test for continuous outcomes, and chi-square test for between-group differences.*
***Results**: A total of 86 patients met inclusion criteria with 43 patients in the weight loss service group (intervention) and 43 patients in the primary care group (standard care). The intervention group had a significantly higher baseline weight and BMI than the standard care group (120.44 kg vs. 95.72 kg, p <0.001 and 45.34 kg/m^2 vs. 37.62 kg/m^2, p <0.001 respectively). The percent change in weight from baseline in the intervention group was a decrease of 3% compared to a decrease of 0.35% in the standard care group (p=0.03).*
***Conclusions**: Involvement of clinical pharmacist in interdisciplinary weight loss management through pharmacotherapy and other medication related services, shows considerable improvement in weight loss, when compared to the standard care of weight management. However, prospective randomized studies are warranted to further assess the benefits of a pharmacist-driven, interdisciplinary weight loss service.*

Keywords: Weight management, Pharmacist service

Background

Obesity is a common, serious, and expensive medical condition. Medical expenses of patients who are obese or overweight are significantly higher compared to those of normal weight; it continues to increase.[1] According to the Centers of Disease Control and Prevention (CDC), from 1999 to 2018, the prevalence of obesity increased from 30.5% to 42.4%, and the prevalence of severe obesity increased from 4.7% to 9.2%.[2] Several studies have shown that abnormal fat distribution that occurs in obesity promotes chronic proinflammatory, prothrombotic, and vasoconstrictive states; therefore, putting those patients at a higher risk of additional comorbidities such as coronary heart disease, hypertension, stroke, type 2 diabetes, etc.[3] Many medical problems can be improved with weight loss. According to the American College of Cardiology, American Heart Association Task Force, and the Obesity Society (ACC/AHA/TOS) clinical practice guidelines for obesity, overweight is defined as body mass index (BMI) ≥25 kg/m^2, and obesity as a BMI ≥30 kg/m^2. The recommended initial goal is a minimum of 5% weight loss within six months by implementing lifestyle changes, with an emphasis on a reduced-calorie meal plan, increasing physical activity, and incorporating behavioral modifications. If patients fail to lose 5% body weight after six months of lifestyle changes, pharmacotherapy can be initiated as an adjunct to those lifestyle changes.[4] There are currently five FDA-approved medications used for chronic weight management; orlistat, phentermine-topiramate, naltrexone-bupropion, liraglutide, and most recently, semaglutide.[5] Lorcaserin was previously available for weight management; however, it was withdrawn from the market in February 2020 due to an increased risk of cancer.[6]

Previous studies have assessed the effects of an interdisciplinary weight loss service involving a physician or that were conducted in the community pharmacy setting. A study conducted at an outpatient university-based, multidisciplinary weight loss clinic in New York was organized by a physician specializing in nutrition. This clinic also involved a pharmacist and a behavioral psychologist. Ninety patients were required to attend one-hour group sessions, where they were weighed then educated about nutrition, exercise, medications, and nutritional supplements. At weeks 10 and 20, the remaining 39 patients that made it to follow-up, had a significant decrease in weight from baseline and patients reported improvement in health-related quality of life, binge-eating behavior, and

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depressive symptoms (p <0.05).[7] Another study recruited 30 patients on orlistat from a specialist clinical nutrition outpatient clinic for weight management. These patients were given the option to receive guidance from a community-based pharmacist in their area (n=15) or not receive guidance (n=15). Patients in the pharmacist guidance group had significantly greater persistence with orlistat therapy that was assessed by duration of therapy (p=0.006) and the number of patients completing the 26-week study (p=0.046); however, there was no difference seen in weight loss between the two groups (p>0.05).[8]

Prior to our analysis, internal, unpublished research was conducted in the JFK Clinic one year after the weight loss service was established. Patients enrolled in the interdisciplinary weight loss service were compared in a 1:2 ratio to the control group receiving standard primary care. A total of 69 patients were included, 22 patients in the weight loss service group and 47 patients in the standard care group. It documented a significant difference in percent weight loss from baseline between the two study groups. The percent change in weight in the patients managed by the interdisciplinary weight loss service (intervention group) was a decrease of 2.27% from baseline compared to an increase of 0.83% from baseline in the patients receiving standard primary care (standard care group); (p<0.001).[9] The purpose of our study was to assess the benefit of this service 5 years after establishment and to contribute to the limited literature available that analyzes the benefit of a pharmacist-driven, interdisciplinary weight loss service, in an ambulatory care setting.

Objective

The objective of this study was to determine the impact of an established, interdisciplinary, pharmacist-driven weight loss service on reaching the goal weight loss of ≥5% in patients who were obese or overweight compared to those who received standard weight loss care.

Methods

Study Area

The John Fitzgerald Kennedy (JFK) Clinic is a hospital-based internal medicine clinic that provides comprehensive medical care to uninsured and underinsured patients in the St. Louis region of Missouri. The clinic features an outpatient pharmacy that provides each prescribed medication for a $5 co-pay to uninsured patients. The pharmacist-led weight loss service within the Mercy JFK clinic accepts patients by referral from their primary care physician. The service consists of the clinical pharmacy team and dietician, who work together to manage the patient monthly; the patient meets with the pharmacist and dietician individually every alternating month. The clinical pharmacist meets with the patient for approximately 30 minutes where they use motivational interviewing techniques to address barriers, motivations, and goal setting. The pharmacist offers methods to alter lifestyle and may recommend a weight loss medication if indicated. Lifestyle modifications are encouraged for the first six months aiming for a weight loss goal of greater than 5% from baseline weight. After 6 months, patients that do not reach the original 5% weight loss goal are offered liraglutide, the clinic's only weight loss medication option. Liraglutide is a glucagon-like peptide-1 receptor agonist that is administered subcutaneously once daily and is also approved for the treatment of diabetes. If patients do not achieve at least 4% of baseline body weight loss after 12 weeks at the maximum tolerated dose or 16 weeks after initiation of therapy, the medication is discontinued.

Study Design

This single-center, retrospective, observational study was submitted and granted exemption by all applicable Institutional Review Boards and confirmed to all standards of the US Federal Policy for the Protection of Human Subjects.

Study Population/Inclusion criteria

Patients included in this study were 18 years of age and older and had a BMI ≥30 or BMI ≥27 with at least one weight-related comorbidity such as hypertension, Type 2 Diabetes Mellitus and Dyslipidemia, referred to the Mercy JFK Weight Loss Management Services from September 1, 2017, to September 30, 2020, whose primary care was managed by Mercy Hospital JFK Internal Medicine clinic, and had at least 2 documented office visits in 6 months.

Exclusion criteria

Patients who were pregnant, concurrently taking another FDA-approved weight loss medication, and/or concurrently taking weight loss supplements were excluded.

Procedures

The weight loss service patients (intervention group) that received a referral in the electronic medical record (Epic) from their primary care physician for weight loss between September 1, 2017, to September 30, 2020, were identified. Patients managed solely by their primary care physician (standard care group) were identified using ICD-10 codes for obesity or overweight within the same time frame. Standard care group patients were then selected using a random number generator. Data collected from qualifying patient's medical records included date of birth, race (defined as Caucasian, African American, Hispanic), sex, height, weight, and co-morbid conditions or medications that affect weight. Co-morbid conditions that affect weight were defined in Table 1. Medications that affect weight were defined in Table 2. Eligible and qualifying patients in each group were compared in a 1:1 ratio and last observations were carried forward.

Outcomes

The primary outcome assessed was percent weight loss from baseline weight in the intervention group versus the standard care group in 6 months. The secondary outcomes assessed the number of patients who had a ≥5% weight loss in the intervention group versus the standard care group in 6 months,

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and for the intervention group: number of dietician visits per patient, number of pharmacist visits per patient, number of patients who received liraglutide and percent weight loss in those patients prescribed liraglutide.

Statistical Analysis

Baseline characteristics were analyzed using a chi-square test or t-test, where appropriate. Primary and secondary outcomes were analyzed using a student's t-test. A modified intention to treat (mITT) approach was used to analyze all patients in the intervention group with at least two office visits. The a priori significance level was 0.05.

Results

A total of 43 weight loss service patients were included and 43 standard care group patients were included in the study (Figure 1).

Baseline Characteristics

Baseline characteristics were similar between both groups; however, the mean weight and BMI for the intervention group were significantly higher than the standard care group (120.4 kg vs. 95.7 kg, p <0.001 and 45.3 kg/m^2 vs. 37.6 kg/m^2, p <0.001 respectively). Most included in the study were Caucasian women between 50-54 years old. A total of 67% and 60% were taking a weight affecting medication in both the intervention and standard care groups, respectively. The most common weight-affecting medication used was insulin and the most common co-morbid weight-affecting condition was depression (Table 3).

Outcomes

The percent weight loss from baseline weight at 6 months was higher in the weight loss service group vs. the standard care group (3.0 ± 5.7 vs. 0.35 ± 5.4, p= 0.03, respectively). A total of 30% of the patients in the intervention group achieved a 5% weight loss, while only 9% of patients in the standard care group achieved this goal (p<0.001) Additionally, the 12 patients who received liraglutide lost an average of 2.9% of their baseline weight (Table 4).

Discussion

Currently, there is limited literature available that evaluates the effectiveness of an interdisciplinary weight loss service in the ambulatory care setting. As previously mentioned, our internal analysis conducted in the Mercy JFK clinic showed that a pharmacist-driven interdisciplinary weight loss service had a positive impact on weight loss outcomes. In this larger, follow-up study, it was also seen that the interdisciplinary approach to weight loss was associated with a statistically significantly greater weight loss, from baseline, than the standard-of-care approach (3.0% vs. 0.35% respectively, p < 0.03). While many of the patients did not meet the guideline-recommended goal of ≥5% of total body weight loss in six months, AHA obesity guidelines have stated that sustained weight loss of 3-5% is likely to result in clinically meaningful reductions in triglycerides, blood glucose, hemoglobin A1c, and the risk of developing type 2 diabetes.[10]

Of the patients that received liraglutide for weight loss, a reduction of 2.9% of their baseline weight was observed in 6 months. This is lower than what was reported in the SCALE trial, a randomized controlled trial in which obese patients with prediabetes received either liraglutide 3mg or placebo for 56 weeks. [11] After 24 weeks of treatment in the SCALE trial, patients lost approximately 7% of their baseline weight.[11] A difference in the two studies is noted in the baseline weight and BMI. Patients in this study had higher baseline weight and BMI than patients in the SCALE trial (120.4 kg vs. 106.2 kg and 45.3 kg/m^2 vs. 38.3 kg/m^2, respectively). Additionally, patients from the Mercy JFK Clinic were of low economic status who may have a higher prevalence of obesity.[12] This can lead to barriers in care such as loss to follow-up due to outside factors such as lack of transportation.

Limitations

There are several limitations to this study. First, the BMI between both groups was not matched which accounts for the large discrepancy between both groups. Patients in the intervention group had a higher baseline weight and BMI, which may indicate that they were referred to the weight loss service due to being considered "higher risk." Although there was no difference in the use of weight-gaining medication or comorbid conditions between both groups, this could influence a patient's ability to lose weight. Additionally, patients enrolled in the weight loss service may be more motivated, than the standard care group; therefore, there is the possibility of selection bias. Other limitations include a single-institution setting, the study was not powered with respect to sample size selection, and many patients were affected by the COVID-19 pandemic. Through information obtained in clinical practice, many patients reported undesired weight gain due to stress, lack of exercise, unhealthy changes in eating habits, and increased alcohol consumption, during the pandemic. Overall, this outcome achieved significance, implying that behavioral modifications, dietary changes, and goal setting have benefits and could be generalized to weight management interdisciplinary teams.

Conclusions

Overall, this small study suggests clinical benefit of an interdisciplinary, pharmacist-driven, weight loss service. Future studies should focus on how a pharmacy-led weight loss service could be successfully implemented in the ambulatory care setting. This study demonstrates that for patients to be successful with weight loss, motivational interviewing and close follow-up by a pharmacist may enhance results. Larger, prospective studies that also measure metabolic markers, such as HbA1c, blood pressure readings, and lipid levels are needed for a longer duration of time to evaluate the impact of this approach on weight loss.

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Table 1: Comorbid Conditions that may affect weight/metabolism

Conditions
• Binge Eating • Bulimia/anorexia • Cushing's syndrome • Depression • Growth hormone deficiency • Hypothyroidism • Insulinoma • Leptin deficiency • Overeating • Polycystic ovarian syndrome (PCOS) • Schizophrenia • Thyroid disorders

Table 2: Medications that affect weight/metabolism

Medication Class	Examples
Thyroid agents	
Antidiabetic agents	• Meglitinides Sulfonylureas • Thiazolidinediones (TZDs) • Alpha-glucosidase inhibitors • Pramlintide • Sodium-glucose cotransporter-2 inhibitors (SGLT-2 inhibitors) • Metformin • Glugacon-like-peptide-1-receptor-agonists (GLP-1 agonists) • Insulin
Cardiovascular agents	• Atenolol • Metoprolol • Propranolol
Antidepressants	• Mirtazapine • Tri-cyclic antidepressants (TCAs) Paroxetine • Bupropion
Anticonvulsants	• Carbamazapine • Gabapentin • Pregablin • Valproic acid
Antipsychotics	• Clozapine • Chlorpromazine • Olanzapine • Quetiapine • Risperidone
Chronic system steroids	
Medroxyprogesterone	
Estrogens	
Progestins	
Testosterone	
Lithium	
ADHD agents	

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Table 3: Baseline Characteristics

Characteristic	Intervention Group (n = 43)	Control Group (n = 43)	p-value
Age, years ± SD	50.2 ± 14.7	54 ± 15.3	0.23
Sex no., (%) • Women • Men	 37 (86) 6 (14)	 32 (74) 11 (26)	0.08
Race, no., % • Hispanic • Caucasian • African American	 11 (26) 22 (51) 10 (23)	 16 (37) 21 (49) 6 (14)	0.12
Baseline weight, kg ± SD	120.4 ± 24.6	95.7 ± 20.5	<0.001
Baseline BMI, kg/m^2 ± SD	45.3 ± 8.1	37.6 ± 8.4	<0.001
On a medication that affects weight, no., %	29 (67)	26 (60)	0.35
Co-morbid condition that affects weight, no.%	24 (56)	19 (44)	0.12

Table 4: Results

Outcome	Intervention Group (n = 22)	Control Group (n = 47)	*p*-value
Primary Outcome			
Percent weight loss from baseline at 6-month follow-up, mean ± SD	3.00 ± 5.7	0.35 ± 5.4	0.03
Secondary Outcomes			
Number of patients to achieve ≥5% weight loss at 6 months, no., %	13 (30)	4 (9)	<0.001
Pharmacist visits per patient in 6 months, mean ± SD	4 ± 2	-	-
Dietician visits per patient in 6 months, mean ± SD	3 ± 2	-	-
Number of patients started on liraglutide after 6 months, no., %	12 (28)	-	-
Percent weight loss in patients prescribed liraglutide, mean ± SD	2.9 ± 2.2	-	-

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Figure 1: Patient Results