Practical Application of a Comprehensive Weight Management Program in Patients with and without Metabolic Syndrome

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Abstract

This paper examines weight loss outcomes and their impact on risk factors associated with metabolic syndrome following participation in OPTIFAST®, a comprehensive weight-management program. A multicenter, retrospective chart review of 153 patients enrolled in the OPTIFAST program was conducted. Change in weight, body mass index, percent weight loss and cardiometabolic risk factors were compared between patients with and without metabolic syndrome. Patients with metabolic syndrome at baseline lost 21.6 ± 10.0 kg compared to 20.4 ± 9.2 kg for patients without metabolic syndrome (p > 0.05). Mean reduction in body mass index was 7.3 ± 3.1 kg/m² and 7.1 ± 3.0 kg/m², and mean percent weight loss was 16.7 ± 6.9% and 17.6 ± 6.9%, respectively (p > 0.05). Metabolic syndrome patients had significantly greater reductions in triglycerides (p < 0.0001) and diastolic blood pressure (p < 0.01). The proportion of metabolic syndrome patients at program completion (41/87 (47%)) was significantly less than the proportion of metabolic syndrome patients at baseline (51/87 (59%); p < 0.0001). Patients with and without metabolic syndrome achieved significant weight loss and similar declines in body weight, body mass index and percent weight change. Significant improvements in cardiometabolic risk factors, including meaningful reductions in the prevalence of metabolic syndrome within the study population were observed.

Abbreviations: BIA: Bioelectrical Impedence Analysis; BMI: Body Mass Index; CFR: Code of Federal Regulations; HDL: High-Density Lipoprotein; HIPAA: Health Insurance Portability and Accountability Act; IRB: Institutional Review Board; MS: Metabolic Syndrome

Introduction

As the prevalence of obesity has increased [1-4], the proportion of individuals with class III obesity (defined by the World Health Organization as body mass index (BMI) ≥ 40 kg/m² [1]) has also increased [5,6]. This has resulted in a greater burden on the healthcare system due to the increased need for treatment of associated co-morbidities, such as type 2 diabetes, hypertension, cardiovascular disease, and disability [7]. The prevalence of metabolic syndrome (MS), defined as a collection of risk factors including low high-density lipoprotein (HDL) cholesterol, elevated triglycerides, elevated blood pressure, central adiposity, and elevated fasting blood glucose associated with increased risk for cardiovascular disease and type 2 diabetes [8], has been increasing simultaneously in populations around the world [8-10]. However, the global prevalence of MS is difficult to estimate as a uniform definition has only recently been established [8] and the prevalence of the components of the syndrome, as well as the syndrome as a whole, is highly variable among different ethnic populations [11].

Due to the high prevalence and increasing severity of obesity, and the concurrent increase in prevalence of MS, the identification of safe and effective treatments for obesity and associated risk factor reduction is essential. Although bariatric surgery is generally accepted as a good treatment option for individuals with class III obesity and individuals with class II obesity (BMI between 35.0 and 39.9 kg/m² [1]) who have associated serious comorbidities, it may not be appropriate for all patients. A patient may not undergo surgery for a number of reasons, including choosing not to assume the risks involved, having medical contraindications to surgery, or having previously undergone a bariatric procedure with subsequent weight regain. Recent randomized clinical trials have shown that medical weight management programs utilizing meal replacements can be effective in producing clinically significant weight loss in individuals with severe obesity [12,13]. Furthermore, previous examinations of the outcomes associated with the use of meal replacements show greater weight loss and weight loss maintenance compared to conventional low calorie diets [14-16]. However, there are few published evaluations of the impact of full meal replacement medical weight management programs implemented in clinical practice settings on weight and other risk factors. There are also few reports of outcomes associated with full meal replacement programs in high risk populations, such as those with MS.

This study investigates the use of a standardized full meal replacement program in the clinical practice setting. OPTIFAST® (Nestlé HealthCare Nutrition, Inc., Florham Park, New Jersey, United States) is a comprehensive medically monitored weight management program for individuals with a BMI ≥30 kg/m². The program uses stimuli-narrowing, full meal replacement products (800-1,280 kcal/day) in combination with nutrition and exercise education and support for behavior modification. Weight loss outcomes associated with implementation of the OPTIFAST program in four US clinics for all patients enrolled during a specific time frame are examined. In addition, the impact of weight loss on risk factors associated with MS is reported.

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Materials and Methods

Patient population

A retrospective chart review was conducted at four US clinical sites from March 2009 to July 2009 to assess the effectiveness of the OPTIFAST weight management program in reducing weight and other disease risk factors as carried out in standard clinical practice. A power analysis was performed to determine the total sample size required to achieve significant results in weight change at program completion compared to baseline (assumptions included standard deviation of the difference equal to 18 kg and absolute difference in weight greater than 9 kg). In order to have 90% power to detect this difference, a minimum of 44 subjects were required at a two-sided significance level of 0.05. A larger study sample size was desired in order to obtain a representative sample from each of the participating institutions; therefore, at each of the four study centers, medical records from the first 40 patients who met the pre-specified inclusion criteria were selected for review. The final sample size of 153 had greater than 99% power to detect the pre-specified difference of 9 kg. Medical records were included in the review if the patients met all of the following criteria: 1) enrolled in the OPTIFAST program between January 1, 2006 and June 30, 2006; 2) were not using appetite suppressants or other weight loss medications concurrently; 3) completed the first phase of the program; and 4) completed the second phase of the program and had at least a weight measurement available at the end of the second phase.

Medical record identification, retrospective chart review and data extraction were conducted in compliance with each of the clinical site's specific IRB requirements. At all clinical sites, a waiver for patient informed consent and HIPAA authorization was granted, as the study design and investigational plan met the requirements for waiver under recognized US guidelines (45 CFR 46.116(d), 45 CFR 165.512(i) and 164.514; [17]).

Intervention

Study subjects were participants in the OPTIFAST program, a comprehensive, physician-managed weight management program which includes medical monitoring, nutrition and exercise education, support for behavioral modification and lifestyle change, and a full meal replacement diet. As obesity is a multifactorial disease with individual variation, the program encourages individualization per participant needs as identified by the program's health-care practitioners, which in addition to a physician may include registered dietitians, behaviorists and exercise therapists.

The food component of the program incorporates the principle of stimuli-narrowing by limiting the variety and quantity of available foods and flavors to decrease caloric intake. This approach reflects research in the area of sensory-specific satiety, which has shown that as a food is eaten its taste and appearance decreases in pleasantness while the pleasantness of other foods, remains relatively unchanged. As a result, food intake at a meal containing a variety of foods may be higher than during a meal with one food [18,19].

The OPTIFAST program consists of two phases. The Active Weight Loss Phase (first phase) lasts approximately 12 weeks, and the Transition Phase (second phase) is approximately 6 weeks in duration. However, the duration of each phase varies based on each clinic's defined protocol for implementation of the program and the patients' progress throughout the course of the program.

During the Active Weight Loss Phase, patients are prescribed one of four low calorie dietary protocols consisting only of OPTIFAST meal replacement products, and no other supplemental foods, providing a total caloric intake of 800 to 1,280 kcal/day. Approximately 35% of the calories are from protein, 50% from carbohydrate and 15% from fat. Patients are advised to consume a minimum of 70 grams of protein per day. In general, the 800 kcal/day protocol is prescribed to patients with a BMI less than 40 kg/m^2, 960 kcal/day to individuals with a BMI between 40 and 44 kg/m^2, 1,120 kcal/day to patients with a BMI between 45 and 49 kg/m^2, and 1,280 kcal/day to persons with a BMI greater than 50 kg/m^2. The clinician uses these BMI guidelines, along with clinical judgment, to determine each patient's dietary protocol. The clinician has the flexibility to change the patient's dietary protocol during the course of the Active Weight Loss Phase if deemed medically necessary or to improve patient progress during this phase of the program.

Patients move into the Transition Phase following completion of the Active Weight Loss Phase. The primary objective of the Transition Phase is to reintroduce a limited spectrum of food into the patients' dietary pattern that promotes ongoing weight loss. By the end of the phase, patients will have a total caloric intake of approximately 1,200 to 1,600 kcal/day, depending on the baseline caloric prescription, with continued use of limited food choices and meal replacements based on clinician recommendations.

In conjunction with the dietary prescription, a behavioral intervention, which includes nutrition and exercise education as well as tools for behavior modification, is implemented as part of the OPTIFAST program. The program incorporates individualized weight loss counseling and may include one-on-one sessions with a physician, registered dietitian or lifestyle counselor; small group discussions led by a health-care professional; or peer support from current and past program participants. Activity plans are customized according to the patient's fitness level and schedule.

Throughout their participation in the program, medical oversight is provided to the patients by program clinicians. This includes regular consultations and laboratory testing to monitor the participants' progress, as well as medication management, which is done in collaboration with the participants' primary health care providers.

Data abstraction procedures

Data from eligible medical records were extracted by trained and qualified clinical researchers. Non-identifiable demographics, height, weight, waist circumference, percent body fat (collected via bioelectrical impedence analysis (BIA), skinfold, or other methods as determined by the clinical center), blood pressure, pulse, co-morbidities, medication usage, lab values such as blood lipid and glucose levels, and the recommended OPTIFAST protocol (kcal/day) were collected at baseline, weeks 2, 4, and 8, Active Phase completion, program completion (defined as completion of the Transition Phase), at 1 year, and at the last available clinic visit. The completion of the Active and Transition Phases was defined by each of the clinical sites' program and patient-specific requirements for phase completion.

Data were recorded on paper case report forms created for the study and entered into a database compliant with US Code of Federal Regulations, Title 21, Part 11 [20].

Statistical Analysis

The statistical significance of change in weight (absolute and percent), BMI and other cardiometabolic risk factors from baseline to program completion was determined for the entire study population using two-sided t-tests. Statistical significance was indicated with a p-value less than 0.05.

Data were available to determine MS status in a subset of the study population. The combined International Diabetes Federation and American Heart Association/National Heart, Lung and Blood Institute criteria were used for determination of MS [8]. Patients were considered to have MS if the patient had at least three of the following risk factors: 1) waist circumference ≥ 102 cm in males and ≥ 88 cm in females; 2) triglycerides ≥ 150 mg/dL, or current use of medication for elevated triglycerides; 3) HDL cholesterol < 40 mg/dL in males and < 50 mg/dL in females, or current use of medication for low HDL cholesterol; 4) systolic blood pressure ≥ 130 mmHg and diastolic blood pressure ≥ 85 mmHg, or current use of antihypertensive medication; or 5) fasting blood glucose ≥ 100 mg/dL, or current use of medication for elevated blood glucose [8]. Patients with type 2 diabetes were assumed to have MS and included in the analyses without consideration of data available for each of the five MS components.

For those study patients whose MS status could be determined, subset analyses were performed. First, two-sided t-tests were performed to test for significant change in weight, BMI, percent weight loss and MS risk factors from baseline to program completion in patients with and without MS. Patients were included in the analysis if they had data available for at least three out of the five MS risk factors at baseline and a decision about MS status could be made, or if a patient had known type 2 diabetes at baseline (n = 126). Second, a Pearson chi-square test was performed to determine if the proportion of patients with MS at program completion compared to the proportion of patients with MS at baseline was significantly different. Patients included in this analysis had to have known MS status at baseline and program completion (n = 87).

In addition, several covariates of interest that have been shown to be related to MS (i.e. age, gender, weight change and baseline BMI) were tested to determine the extent to which they accounted for the change in the number of the patients' MS risk factors [21,22]. Only the MS factors from patients with data available for the specific MS factor at both time points were considered in the analysis. Lastly, change in each specific MS risk factor that may be dependent on medication usage (i.e. triglycerides, HDL cholesterol, blood pressure and fasting blood glucose) was modeled as a function of the covariates mentioned above and reported relevant baseline medications.

Results

A total of 153 patients' medical records were reviewed. Ninety-nine of the patients were female (64.7%) and the average age at program enrollment was 46.7 ± 10.8 years. Enrollment was equally distributed across all four investigational sites. The majority of the patients were prescribed the 960 kcal/day protocol at baseline, followed by the 800, 1,120 and 1,280 kcal/day protocols (Table 1).

Mean weight at baseline was 122.4 ± 26.1 kg, with mean BMI of 42.5±7.8 kg/m^2. Absolute mean weight loss from baseline to program completion was 21.2 ± 11.3 kg ($p < 0.0001$), which translates to a 17.1% loss of initial weight ($p < 0.0001$). More than 87% of patients lost greater than or equal to 10% of their body weight at program completion (Figure 1). BMI was also significantly reduced by 7.3 ± 3.6 kg/m^2 ($p < 0.0001$) from baseline to program completion. Significant reductions from baseline were also noted in waist circumference, systolic and diastolic blood pressure, lipid levels and blood glucose levels for the entire study population at program completion ($p < 0.05$; Table 2).

Follow-up data greater than or equal to six months after program completion (mean 111.4 weeks) were available for thirty patients (19.6%). At their last follow-up visit, these patients had maintained a mean weight loss of 16.3 ± 16.4 kg ($p < 0.0001$), losing on average 12.0% of their initial body weight ($p < 0.0001$). A weight loss of ten percent or

OPTIFAST Protocol at Baseline (kcal/day)	MS at Baseline (N=80)	No MS at Baseline (N=46)	Unknown MS at Baseline (N=27)	Total Patients (N=153)
800	10 (12.5)	10 (21.7)	7 (25.9)	27 (17.7)
960	61 (76.3)	36 (78.3)	16 (59.3)	113 (73.9)
1,120	8 (10.0)	0 (0.0)	4 (14.8)	12 (7.8)
1,280	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)

kcal = kilocalorie; MS = Metabolic Syndrome

Table 1: Prescribed Energy Intake at Baseline.

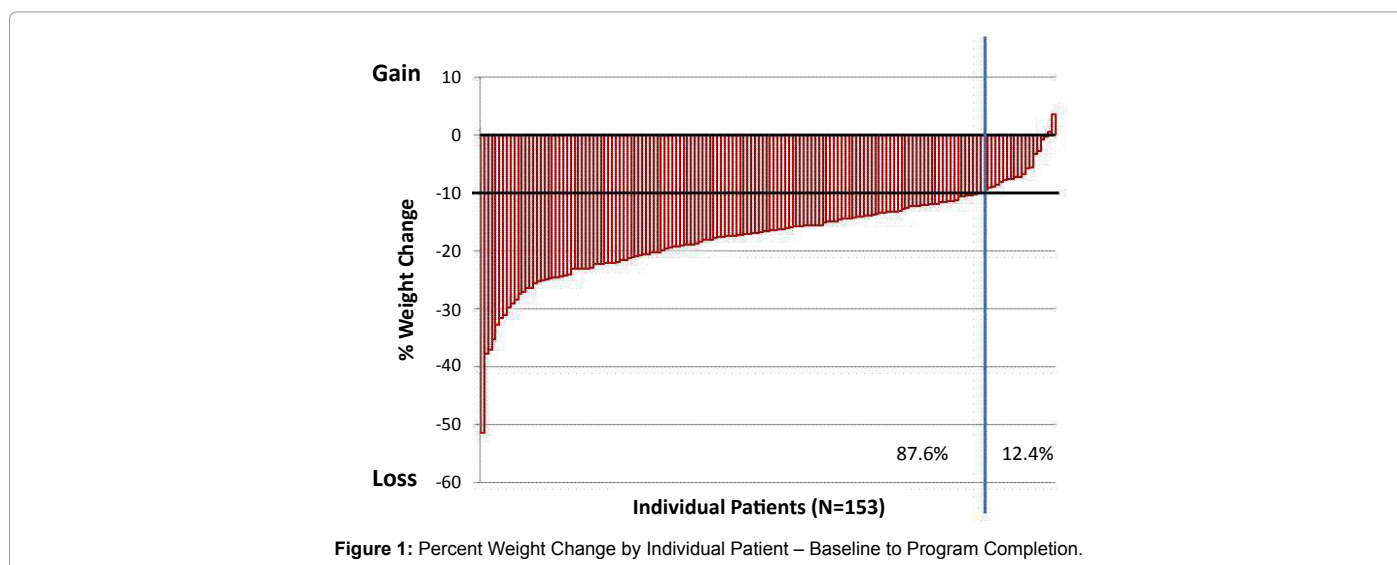**Figure 1:** Percent Weight Change by Individual Patient – Baseline to Program Completion.

Risk Factor	Baseline	Program Completion
BMI (kg/m²)		
N	153	153
Mean (SD)	42.5 (7.8)	35.2 (7.5)
Change from Baseline[a]	—	-7.3 (3.6)[d]
Waist Circumference (cm)		
N	111	85
Mean (SD)	123.2 (18.3)	106.9 (15.24)
Change from Baseline[a]	—	-18.3 (8.6)[d]
Blood Pressure (systolic/diastolic) (mmHg)		
N	152	149
Mean (SD)	126.9 (13.5) / 75.8 (10.3)	118.8 (12.8) / 71.0 (11.2)
Change from Baseline[a]	—	-8.1 (15.3)[d] / -5.1 (15.7)[c]
Fasting Glucose (mg/dL)		
N	98	71
Mean (SD)	102.7 (24.7)	95.5 (21.3)
Change from Baseline[a]	—	-5.9 (20.3)[b]
Total Cholesterol (mg/dL)		
N	143	131
Mean (SD)	191.3 (40.5)	172.5 (39.1)
Change from Baseline[a]	—	-19.7 (34.3)[d]
LDL Cholesterol (mg/dL)		
N	124	130
Mean (SD)	113.1 (35.7)	104.1 (32.2)
Change from Baseline[a]	—	-11.1 (30.3)[c]
HDL Cholesterol (mg/dL)		
N	138	130
Mean (SD)	47.1 (13.6)	45.8 (12.2)
Change from Baseline[a]	—	-1.6 (8.6)[b]
Triglycerides (mg/dL)		
N	141	131
Mean (SD)	156.3 (86.0)	113.0 (55.0)
Change from Baseline[a]	—	-36.5 (59.6)[d]

[a]Change from Baseline is presented as Mean (SD)
[b]Significant difference from Baseline to Program Completion by t-test, p<0.05
[c]Significant difference from Baseline to Program Completion by t-test, p<0.001
[d]Significant difference from Baseline to Program Completion by t-test, p<0.0001
BMI = Body Mass Index; SD = Standard Deviation

Table 2: Change in Cardiometabolic Risk Factors from Baseline to Program Completion.

Baseline Characteristic	MS at Baseline (N=80)	No MS at Baseline (N=46)	Total (Known MS Status at Baseline) (N=126)
Gender (Female (%))	48 (60%)	31 (67%)	79 (63%)
BMI (Mean (SD))	43.8 (7.6)	40.5 (8.0)	42.6 (7.9)
Weight, kg (Mean (SD))	129.0 (25.9)	114.7 (23.8)	123.8 (26.0)

MS = Metabolic Syndrome; SD = Standard Deviation

Table 3: Baseline Demographics by Metabolic Syndrome Status.

greater was maintained by 46.7% of these patients at their last follow-up visit.

Data were available to determine the MS status in 126 patients at baseline (Table 3). Of those, eighty patients (63.5%) had MS and 46 patients (36.5%) did not. The majority of the patients whose MS status was known at baseline were female (63%). On average, subjects with MS at baseline had a slightly higher baseline weight and BMI than subjects without MS.

The mean reduction in weight from baseline to program completion was 21.6 ± 10.0 kg for patients with MS and 20.4 ± 9.2 kg for patients without MS at baseline. The difference in weight loss between the two groups was not statistically significant (p = 0.5007). Patients with and without MS at baseline had similar declines in BMI from baseline to

program completion; BMI decreased 7.3 ± 3.1 kg/m² and 7.1 ± 3.0 kg/m² for patients with and without MS at baseline, respectively (p = 0.7418). Percent weight loss from baseline to program completion also did not statistically differ between patients with and without MS at baseline. Patients with MS at baseline had a mean loss of 16.7 ± 6.9% of their initial weight, and patients without MS lost 17.6 ± 6.9% of their initial weight (p = 0.4888).

Likewise, with the exceptions of significantly greater reductions in triglycerides (p < 0.0001) and diastolic blood pressure (p < 0.001) in patients with MS compared to patients without MS at baseline, the reduction in all other MS risk factors from baseline to program completion was similar for both groups (Table 4). In patients with MS at baseline (N = 80), waist circumference, triglycerides, systolic and

Risk Factor	MS at Baseline (N=80)		No MS at Baseline (N=46)		p-value for differences between groups
	Baseline	Program Completion	Baseline	Program Completion	
Waist Circumference (cm)					
N	66	51	31	27	
Mean (SD)	126.5 (18.6)	109.1 (15.8)	119.2 (17.8)	103.3 (15.1)	
Change from Baseline[a]	–	-18.7 (9.0)[d]	–	-17.8 (8.2)[d]	0.6623
Triglycerides (mg/dL)					
N	78	66	46	43	
Mean (SD)	188.7 (95.3)	124.1 (55.2)	104.3 (38.0)	95.8 (53.3)	
Change from Baseline[a]	–	-57.9 (64.8)[d]	–	-7.8 (43.1)	<0.0001
HDL Cholesterol (mg/dL)					
N	76	66	46	43	
Mean (SD)	41.4 (10.5)	40.3 (10.9)	57.3 (12.4)	52.7 (10.5)	
Change from Baseline[a]	–	-0.8 (8.1)	–	-3.7 (9.1)[b]	0.0876
Blood Pressure (systolic/diastolic) (mmHg)					
N	80	77	46	45	
Mean (SD)	131.1 (14.2)/ 77.5 (11.6)	121.8 (15.0)/ 69.8 (12.5)	121.9 (8.6)/ 71.9 (8.5)	116.1 (8.1)/ 73.0 (10.4)	
Change from Baseline[a]	–	-9.7 (18.1)[d]/ -8.2 (17.9)[c]	–	-5.6 (9.2)[c]/ 1.1 (13.0)	0.1603/ 0.0014
Fasting Glucose (mg/dL)					
N	58	41	33	23	
Mean (SD)	110.6 (28.5)	99.6 (25.7)	90.6 (6.2)	90.0 (8.1)	
Change from Baseline[a]	–	-9.2 (24.3)[b]	–	0.0 (9.0)	0.0549

[a]Change from Baseline is presented as Mean (SD)
[b]Significant difference from Baseline to Program Completion by t-test, p<0.05
[c]Significant difference from Baseline to Program Completion by t-test, p<0.001
[d]Significant difference from Baseline to Program Completion by t-test, p<0.0001
MS = Metabolic Syndrome; SD = Standard Deviation; HDL = high density lipoprotein

Table 4: Mean Change in Metabolic Syndrome Risk Factors from Baseline to Program Completion

diastolic blood pressure and fasting glucose were significantly reduced from baseline to program completion (p < 0.05). In patients without MS at baseline (N = 46), waist circumference and systolic blood pressure were also significantly reduced from baseline to program completion (p < 0.05), while HDL cholesterol levels declined (p < 0.05).

Among the 126 patients with determinable MS status at baseline, the MS status could also be determined at program completion for 87 patients. Among this group, the proportion of patients with MS at the completion of the program (41/87 (47%) was significantly less than the proportion of patients with MS at baseline (51/87 (59%); p < 0.0001). Three patients without MS at baseline developed MS by the completion of the program (3/87 (3.4%)).

A general linear model was fit to model the association between the change in the number of MS factors and the covariates of age, gender, change in weight, and baseline BMI. Baseline BMI and weight change were associated with the change in the number of MS factors patients had at baseline compared to program completion (p < 0.05), such that higher baseline BMI and more weight loss were associated with a larger change in the number of MS factors. In addition, general linear models were fit to model the association between the change in each of the individual MS factors (triglycerides, HDL, blood pressure and fasting glucose) and the covariates listed above. Weight change was associated with change in triglycerides (p < 0.0001) and systolic blood pressure (p < 0.05). Gender was associated with change in HDL cholesterol (p < 0.05), although, the parameter estimates for the effect of gender were not unique for males versus females. None of the covariates of interest were significant predictors of change in diastolic blood pressure and fasting blood glucose from baseline to program completion.

Discussion

Although there are numerous strategies for non-surgical weight reduction, there are few evaluations of actual clinical implementation, and even fewer evaluations of programs that utilize a full meal replacement strategy. This study reports the outcomes associated with routine implementation of a comprehensive, medically monitored weight reduction program including behavioral modification and stimuli narrowing in the form of a low calorie diet using OPTIFAST full meal replacements in four US clinics. On average, the 153 consecutive patients who completed the program were severely obese and experienced a weight loss of 21.2 kg or 17% of their initial body weight over approximately 20 weeks. Patients also experienced significant reductions in cardiometabolic risk factors associated with obesity, including blood pressure, blood glucose, blood lipids, and waist circumference. Perhaps as a result of the high degree of obesity in this sample, a majority of the patients had MS at the initiation of the program. However, by program completion there was a 12% reduction in the subset of patients with MS.

The contemporary re-evaluation of this weight management program provides an opportunity to understand the types of outcomes associated with a behavioral approach to weight reduction in a progressively heavier and more complicated obese patient seeking weight loss. In this clinic based program, 87% of patients lost at least 10% of their initial body weight by program completion. Therefore, a majority of the patients lost clinically significant amounts of weight within 20 weeks. The results of this current study are similar to prior reports of studies evaluating the OPTIFAST program [23-26]. Drawert et al. [23] reported an average weight loss in a sample of 20,307

patients of 23.6 ± 10.5 kg (p < 0.001) following completion of at least 22 weeks of the 420-800 kcal/day OPTIFAST program. Compared to the Drawert et al. [23] study of OPTIFAST, similar levels of weight loss and improvements in cardiometabolic risk factors were achieved even though the participating clinics in this evaluation used 960 kcal/day predominately (no one less than 800 kcal/day) and the current study population had a greater mean baseline weight and BMI (122.4 ± 26.1 kg and 42.5 ± 7.8 kg/m² compared to 111.4 ± 24.6 kg and 39.4 ± 7.3 kg/m²). Mean weight loss in this study also compared favorably to more recent studies in severely obese populations that were medically managed in various settings [12,13].

As the medical system struggles to provide effective weight management solutions for the broader population, the percentage of the population that is considered severely obese is increasing along with associated comorbid conditions and abnormal cardio metabolic risk factors [2,4,10,12]. As a consequence, there will be an increasing need to provide weight loss options that are consistently associated with reductions in risk factors. Due to the increase in prevalence of MS associated with obesity, a subset of 126 patients in this study whose MS status could be determined at baseline was examined to assess any differences in weight loss and risk factors associated with the condition. Of these 126 patients, 63% had MS at baseline. In this study, the average weight loss and improvements in cardiometabolic risk factors associated with MS were similar compared to those who did not have MS [24-26].

Our analysis suggests that for some of the components of MS such as high serum triglycerides and elevated systolic blood pressure, the amount of weight reduction is directly related to clinical improvements in these parameters. While clinically there has been some suggestion that the presence of insulin resistance, a central component of the MS pathophysiology, can impair response to weight reduction strategies, our observations suggest that the calorie restriction provided using meal replacement leads to comparable weight loss in patients with and without MS. Investigators have used meal replacements in several studies as a part of the weight loss strategy in patients with MS with similar outcomes. Flechtner et al. [27] used partial meal replacement intervention (high protein 1.34 g/kg vs. conventional 0.8 g/kg) to reduce weight in obese patients with MS. There was a greater reduction in the prevalence of MS with the higher protein strategy. Lee et al. [28] used partial meal replacement intervention (high protein vs. conventional) in Korean patients with MS. For those assigned to the high protein intervention, there was greater reduction in trunk fat and total fat mass. König et al. [16] studied partial meal replacement compared to a low calorie food-based diet, reporting a 12% decrease in the prevalence of metabolic syndrome in the subjects randomized to partial meal replacement (p < 0.05). Our study supports many of the findings previously published, but is unique in that it involves the implementation of full meal replacement for a period of time in the context of a clinic-based weight reduction program.

Limitations

While this study has many unique observations, it is limited by study design. As a retrospective design, there is not a designated control group or randomly assigned treatment options. Furthermore, there is variability in the implementation of the intervention between and within participating study sites due to the flexibility that has been built into the design of OPTIFAST to facilitate execution of the program at each clinical practice and to meet individual patient needs.

This was an evaluation of clinical practice as implemented in a real-world setting. As such, the patients studied were seeking professional medical assistance with weight reduction, and the extent to which their motivation contributes to the weight loss achieved is unclear. In addition, although the cost of the medical monitoring portion of the program may be covered by insurance, the cost of the meal replacements generally is not covered. Therefore, the extent to which cost restricts access to the program, which could limit the generalizability of the study results, was not assessed.

Additionally, short-term follow up is useful in determining acute weight loss, but longer-term outcomes are desirable. In the subset of patients where long-term data were available, the maintenance of weight loss was significant with more than 10% of initial body weight loss maintained over an average of two years. However, these results may be biased as those patients with long-term weight loss data may have been more likely to have maintained weight loss, or alternatively, to have gained weight. Thus, this subset is too limited to draw any conclusions about long-term effectiveness. There is a need for additional study to understand how extending a behavior modification program for ongoing support beyond the initial implementation of full meal replacement affects long-term outcomes and weight maintenance.

Conclusions

This paper reports the impact of a structured, medically supervised weight loss program as implemented in clinical practice at four US clinics. The majority of the patient population studied was severely obese and had metabolic syndrome. These patients achieved significant short-term weight loss using a full meal replacement approach with a low calorie prescription in conjunction with a comprehensive behavioral therapy program. Significant improvements were also observed in cardiometabolic risk factors associated with obesity, including meaningful reductions in the prevalence of metabolic syndrome within the study population. This analysis highlights the need for additional research based in the clinical practice setting to better inform best practices for obesity management. In order to accomplish more complete long-term follow up and broader generalizability, the fact that current clinical practice does not support long-term treatment of obesity must be addressed. Our data support the idea that medical management and full meal replacement can be successful in achieving clinically relevant amounts of weight loss in severely obese patients. Findings from our study and other trials of longer term weight loss maintenance interventions suggest that the adoption of long-term treatment protocols using meal replacement strategies and behavioral therapy may be a viable strategy for effective clinical management of obesity.

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