Study

Analysis of Medical Outcomes Associated with a Meal Replacement Program for Obese Adults

Data collected by The Hernried Center Study written by Robard Corporation

Abstract

Objective:

To analyze medical outcomes in obese adults following a Very Low Calorie Diet (VLCD) meal replacement program.

Methods:

An observational study evaluated weight loss and medical conditions of 270 obese adults who followed a medically supervised VLCD program that incorporated meal replacements. Individuals with a BMI over 30, or a BMI over 25 with at least one comorbid condition, were eligible for participation. Blood pressure and weight readings were recorded weekly; cholesterol, triglycerides, glucose and alanine aminotransferase (ALT) were collected monthly throughout the program. Initial and final findings were analyzed using correlations and descriptive statistics.

Results:

Subjects lost an average of 19% of their initial body weight (M=46.18 pounds). Among the overall sample, female subjects (n=196) and male subjects (n=74), significant findings were recorded between weight loss, final weight and final BMI for multiple metabolic parameters.

Overall improvements were seen in reductions in systolic and diastolic blood pressure, cholesterol, LDL, triglycerides, glucose and ALT. Final HDL readings were mixed, with higher (improved) readings for male subjects, but lower readings overall for female subjects.

Longevity in the program strongly correlated with weight loss (r=0.51, p < .001). A subset of female subjects who followed a program for more than one-year averaged a 25% weight loss versus a 19% weight loss for female subjects overall. Weight loss was significantly correlated with the number of weeks in program (r=.79, p < .001 with a R2=.624) for these female subjects.

Conclusions:

A physician-monitored meal replacement program incorporating lifestyle changes and physical activity can be an effective means of weight loss and result in positive medical outcomes.

Introduction

Obesity is at epidemic levels both in developed and developing countries worldwide.^{1, 2} Often attributed to overeating, obesity is a chronic disease that extends beyond food choices to include genetics, individual behaviors, socioeconomic factors and physical activity.³ Among the American adult population, 78 million people or roughly 35%, are obese, having a body mass index (BMI) equal to or greater than 30; an additional 76 million are overweight (BMI=24.5-29.9).⁴ This number continues to increase nationwide.⁵

Obesity is linked to six of the top ten leading causes of death among adults, and, is therefore considered one of the most preventable causes of death.⁷ Medical conditions linked to obesity-related mortality include hypertension, high blood cholesterol, low HDL, high triglyceride levels, diabetes, liver disease, arthritis, musculoskeletal disease, and sleep

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apnea, among others.^{8,9} Further, obesity-related health problems are not limited to physical conditions. Depression, discrimination, social stigma, self-esteem issues, and lower quality of life resulting from an inability to participate in social activities also are common among people dealing with obesity.^{10, 11} With 112,000 deaths per year associated with obesity ¹², there are societal benefits to addressing this public health challenge.

Obesity is also costly to society. Health care costs for obese adults are approximately \$190 billion per year.¹³ Compared to normal-weight people (BMI=18.5-24.9), studies find that obese individuals pay between 10-43% more per capita. On average, obese people pay 42% more for health care and 80% more on prescription drugs.¹⁴

There are also additional indirect costs that affect the overall population. Lost productivity, absenteeism from work, limitations due to disabilities, morbidity and mortality create additional wide-scale financial burdens.¹⁵ Obesity costs in the United States are 2-3 times greater than in other developed countries¹⁶, and by 2030, total health care costs attributable to obesity could reach \$861 to \$957 billion.¹⁷

Treating Obesity

While many understand how obesity affects their lives, losing weight is a challenge for many people and maintaining weight loss is even more difficult. Popular weight loss methods include dieting, increased physical activity, bariatric surgery, and use of weight loss supplements, or any combination of these methods.

Dieting

While many factors such as age, gender and level of activity influence the number of calories an individual requires, the United States Department of Agriculture recommends 1,800-2,400 calories per day for women, and 2,200-3,000 calories per day for men.¹⁸ To achieve a weight loss of one pound per week, calorie consumption must be reduced by approximately 500 calories per day.¹⁹

Physical Activity

Alone, and in conjunction with dieting, increased aerobic exercise can lead to weight loss. To lose weight, at least 200 minutes of moderate cardiovascular exercise per week is recommended.²⁰ For obese patients who may have difficulty with flexibility and mobility, successfully adopting such lifestyle changes can be challenging.

Surgical Interventions

Bariatric surgeries, procedures that reduce caloric intake by modifying the anatomy of the gastrointestinal tract, can be an option for patients considered morbidly obese (BMI \geq 40). Views on this more extreme option are mixed. Medical benefits such as reduced or eliminated need for medications to treat diabetes, hypertension and hyperlipidemia, and improvements to sleep apnea also were reported.²¹ However, while efficacy of surgery is high, surgical options are not without risk, including surgical complications, the need for reoperation and mortality.²²

Weight Loss Supplements

Although popular among American adults, the use of over-the-counter diet and weight loss supplements is controversial due to a lack of federal guidelines, unknown health risks and unsubstantiated promises of weight loss.²³ The Food and Drug Administration has expressed concerns about the safety of these products and cautions consumers to beware of "miracle" foods and supplements that promise weight loss.²⁴

Still, supplements used as part of a medically supervised weight loss program have had successful results. Studies find that compared to other weight loss methods, use of meal replacements resulted in significantly greater weight loss, reduced body weight, body fat,²⁵ waist circumference and BMI,²⁶ and improvements in body composition.²⁷ Across studies, higher levels of compliance²⁸ and better weight maintenance results also were reported for participants using meal replacements versus control groups or participants using other weight loss methods.^{29, 30, 31}

The use of meal replacements as part of a medically supervised weight loss program also resulted in various health benefits. These include improved high-density lipoprotein cholesterol concentrations,³² decreased triglycerides, increased HDL levels, reduced insulin and homeostasis model assessment of insulin resistance (HOMA-IR) and lower glucose concentration.^{33, 34}

The findings presented here analyze key weight-related indicators and medical outcomes of obese adults resulting from participation in a meal replacement program under medical supervision. This analysis allows for an evidence-based assessment of outcomes associated with using meal replacements as part of a VLCD among adult obese subjects.

Methods

Participants

Subjects were obese adults who participated in a VLCD program and had a BMI over 30, or a BMI over 25 with at least one comorbid condition. The program offered two meal replacement options. The total meal replacement plan included three meal replacement beverages per day for women and four meal replacements per day for men. A partial replacement plan included two meal replacements daily for women and three meal replacements daily for men, plus a lean protein meal of 200 calories. Once an option was selected, participants followed their identified total or partial meal replacement program for the duration of their participation. When participants reached their goal weight, they entered a maintenance phase, at which time their caloric intake increased.

Additional requirements for participation in the program were weekly medical monitoring and attendance at meetings, 300 minutes of physical activity per week and maintenance of food records. Determination of compliance and weekly reporting was completed by clinic staff; food records were self-reported. Participants who did not attend meetings, comply with their selected meal replacement option or take part in medical monitoring were dropped from the program.

Subjects started their program between February 2013 and December 2016. End dates varied and were recorded when participants ceased participating in the program, which ranged from 10-105 weeks.

All subjects (N=270) consented to allow data associated with their weight loss progress to be used for research purposes. The majority of subjects were female (73%; n=196); the mean age of subjects was 53 years (f: 53; m: 54). The initial weight range of subjects was 171.8 – 509.9 lbs. (M=285.03), and initial BMI range was 26 - 74 (M=38.82). Table 1 summarizes characteristics of subjects.

Table 1Characteristics of Program Subjects

	Total	Female	Male
n	270	196	74
Age (yrs.)	53.27	53.09	53.74
Weight (lbs.)	242.21	226.43	284.01
BMI (kg/M2)	38.81	38.25	40.29
Time in program (wks.)	27.31	29.32	22.00

Data Collection

Data on blood pressure and weight was collected weekly by medical assistants during weekly monitoring sessions at a clinic. Readings for lipids, glucose and ALT was recorded from their monthly lab work or from appointments at their primary care physician's office.

Data Analysis

Descriptive statistics and correlations were reported; correlations include the correlation coefficient (Pearson's productmoment coefficient, r) and the p value (p=statistical significance). Correlations determined relationships between final weight, weight loss and BMI, individually, and the medical conditions reported included blood pressure, cholesterol, triglycerides, glucose and alanine aminotransferase (ALT).

Results

Program Participation

The average length of program participation was 27 weeks (f:29; m:22). Weight loss was strongly correlated to the number of weeks spent in the program for all participants (n=270; r=.51, p <.001) and for females (n=196; r=.58, p <.001); it was moderately correlated for males (n=74; r=.41, p <.001).

Table 2 Difference in Means and Standard Deviations for Multiple Metabolic Parameters

	Initial Weight						Final Weight					
	Total		Females		Males		Total		Females		Males	
	М	SD	М	SD	М	SD	М	SD	М	SD	М	SD
Weight (lbs)	242.21	±57.30	226.43	±45.69	284.01	±63.63	196.19	±52.53	182.28	±42.66	233.04	±58.41
BMI (kg/M2)	38.81	±7.20	38.25	±6.8	40.29	±8.08	31.36	±6.63	30.74	±6.36	32.99	±7.06
Systolic (mm Hg)	129.34	±14.31	127.86	±13.77	133.27	±15.03	118.92	±13.81	117.94	±14.12	121.53	±12.69
Diastolic (mm Hg)	76.96	±9.95	76.22	±10.06	78.92	±9.45	71.17	±9.75	71.57	±9.61	70.14	±10.10
Cholesterol (mg/dL)	191.05	±38.01	191.95	±35.00	188.70	±45.14	173.32	±32.01	176.87	±30.90	163.91	±33.20
HDL (mg/dL)	52.94	±14.75	56.57	±14.89	43.35	±8.97	51.93	±13.14	54.87	±12.80	44.14	±10.68
LDL (mg/dL)	110.31	±32.83	109.81	±30.29	111.68	±39.26	99.87	±27.11	101.29	±26.54	96.01	±28.45
Triglycerides (mg/dL)	131.62	±81.73	121.04	±57.43	159.83	±121.48	104.72	±50.93	102.33	±45.99	111.14	±62.19
Glucose (mg/dL)	101.77	±32.62	100.40	±31.56	105.42	±35.23	89.21	±28.26	87.58	±26.16	93.53	±33.00
ALT (unit/L)	32.18	±26.10	30.26	±28.42	37.26	±17.77	25.14	±14.69	23.54	±11.88	29.39	±19.83

Weight and Body Mass Index Reduction

The average weight at program start was 242.21 pounds (f: M=226; m: M=284;); the final average weight was 196.19 (f: M=182; m: M=233). Individually, subjects (n=268) lost between 3 and 217 pounds (M=46), representing a 19% overall average reduction in weight (f: M=25.7%; m: M=23.1%). Two subjects gained weight (2 lbs.; 10 lbs.).

At the start of the program, the average BMI was 38.81 (f: M=38.3; m: M=40.3). This decreased to 31.36 (f: M=30.10; m: M=33) at the end of the program, a reduction of 20.5% (f: M=21.4% m: M=18.1%). At the end of the program 53% of subjects (n=143) had a BMI <30.

Among the population of subjects, sixteen (f=15; m=1) participated in the program for 52 or more weeks (M=64 weeks). Females in this subset of participants lost 25% of their body weight, compared to 19% for the overall population of women. Weight loss was significantly correlated with the number of weeks in program (r=.79, p <.001 with a R2=.624). Though not significant, there also were reductions in systolic and diastolic blood pressure, triglycerides and glucose, and an increase in HDL levels in this group.

Blood Pressure

Blood pressure readings decreased across participant groups. Initial systolic and diastolic readings were 129 (prehypertensive) and 77, respectively (f: M=128,76; m: M=133,79). Final blood pressure readings for the overall sample were M=119 (systolic) and M=71 (diastolic). Blood pressure readings also improved for both female (M=118, 72) and male (M=122, 70) subjects.

Improvements in blood pressure were correlated with weight loss, final weight and final BMI. Lower readings for both systolic (r=.15, p <.05), and diastolic blood pressure (r=.18, p <.001) were related to weight loss for all subjects collectively, and for female subjects (systolic: r=.18, p <.01; diastolic: r=.21, p <.01).

Final weight was correlated to systolic blood pressure for all subjects (r=.23, p <.001), female subjects (r=.15, p <.05) and male subjects (r=.31, p <.01). Final weight also was correlated with diastolic blood pressure for female subjects (r=.17, p <.05).

Final BMI was correlated with systolic (r=.24, p <.001) and diastolic (r=.16, p <.01) blood pressure for all subjects, and for female subjects (systolic: r=.20, p <.01; diastolic: r=.20, p <.01). BMI also was related to systolic blood pressure for male subjects (r=.30, p <.05).

Cholesterol

Separate readings were taken for total cholesterol, HDL cholesterol and LDL cholesterol. Weight loss was significantly related to improved total cholesterol readings for all subjects overall (r=.22, p <.001), female subjects (r=.19, p <.01) and male subjects (r=.26, p <.05).

HDL Cholesterol

HDL cholesterol is considered "good" cholesterol; that is, lower HDL cholesterol levels are associated with greater health risks. Since HDL levels decreased for all subjects overall (r=.22, p <.001) and women (r=.14, p <.05), weight loss had a negative influence on HDL readings. However, HDL readings for male subjects increased, indicating a positive relationship between weight loss and HDL levels (r=.26, p <.05).

LDL Cholesterol

Final weight was correlated to improved LDL cholesterol readings for male subjects (r=.28, p <.05). BMI also was correlated to improved LDL readings for male subjects (r=.28, p <.05).

Triglycerides

All participants collectively, female subjects and male subjects showed improved triglyceride readings. There was a significant relationship between final weight loss and triglycerides across subjects (r=.24, p <.001), and for female (r=.24, p <.001) and male (r=.27, p <.05) subjects. Final weight had a significant but weak correlation to triglyceride readings for all subjects (r=.14, p <.05) and women (r=.14, p <.05). The relationship between final weight and BMI was similar for the overall sample (r=.16, p <.05) and female subjects (r=.17, p <.05).

Glucose

Glucose readings showed significant reductions in the overall sample. Weight loss was correlated with improved glucose across the sample (r=.24, p <.001) and for female subjects (r=.28, p <.001). Similarly, final weight was correlated with glucose overall (r=.27, p <.001) and female subjects (r=.33, p <.001), as was BMI (population: r=.27, p <.001; f: r=.33, p <.001).

Alanine aminotransferase (ALT)

Average ALT levels improved across groups, however there were no significant findings. Means and standard deviations for initial and final readings for ALT and other medical conditions are presented in Table 2.

Discussion

With more than one-third of the populations considered obese and related costs associated with health care and lifestyle continuing to grow, greater awareness of complications associated with this disease and exploration of treatment options must be considered. The findings reported here indicate that VLCD meal replacement programs can be an effective treatment both for weight loss and healthier medical condition.

Importantly, analysis of participants who followed their weight loss and maintenance program for over a year confirms that adhering to a meal replacement plan significantly influences weight loss and results in other positive outcomes.³⁵ These outcomes include improved readings for blood pressure, cholesterol, LDL, glucose and ALT for both female and male subjects. Further, though often weak to moderate, significant relationships were found between the amount of weight lost (e.g., number of pounds), subjects' final weights and subjects' final BMI to systolic and diastolic blood pressure, cholesterol, LDL, triglycerides and glucose. These results also provide support for previous research that found that people who use meal replacements as a weight loss method followed their program with higher levels of compliance, and better maintained their weight.^{36, 37}

These findings, in combination with the improved readings reported over the course of the program, indicate benefits to participants in terms of weight loss and maintenance, and more importantly, better health. Because adherence to a diet is a key determinant of its success³⁸, a greater awareness of the possible outcomes associated with meal replacements may provide much needed incentive and motivation for obese adults to initiate and follow a program. Given the physical and psychological challenges that confront dieters, this can be an influential stimulus. Further, improvements in these areas benefit not only the individual battling obesity, but also obesity-related spending, which can reduce the projected costs associated with obesity that are borne at a societal level.

To better address the needs of dieting, obese adults, continued research that collects longitudinal data to track program participants can offer greater insights into program success and challenges. A better understanding of why, and at what point in their program, participants lose interest or continue could allow for the development of different programs to address shifting needs. Also, because maintaining weight loss is a greater challenge than losing weight, tracking participants' weight and health over time can help identify dieting and behavioral trends which influence maintenance effectiveness, and allow for opportunities to offer interventions at key milestones.

References

- 1. Uzogara, S. Obesity epidemic, medical and quality of life consequences: A review. International Journal of Public Health Research. 2017; 5:1-12.
- 2. Imes, C. & Burke, L. E. The obesity epidemic: The United States as a cautionary tale for the rest of the world. Current Epidemiology Reports. 2014; 1:82-88.
- 3. Rothacker, D.Q. Five-year self-management of weight using meal replacements: Comparison with matched controls in rural Wisconsin. Nutrition. 2000; 16:344-348.
- 4. American Heart Association. Body mass index in adults. 2016. http://www.heart.org/HEARTORG/HealthyLiving/Weight Management/Obesity/ Obesity-Information_UCM_307908_Article.jsp#.WeZJt2hSzIV. Retrieved 6/6/17.
- 5. Henry, T.A. Obesity rates fall in four states, but overall rates remain high. AMA Wire; American Medical Association. 2016, September 26. https://wire.amaassn.org/delivering-care/obesity-rates-fall-4-states-overall-rates-remain-high. Retrieved 6/6/17.
- 6. These include: heart disease (#1), some cancers (#2), respiratory diseases (#3), stroke (#4), diabetes (#7) and kidney disease (#9).
- 7. U.S. Department of Health and Human Services, Center for Disease Control. CDC National Health Report Highlights. 2014. https://www.cdc.gov/ healthreport/publications/compendium.pdf. Retrieved 6/6/17.
- 8. (4)
- 9. (7)
- 10. (2)
- 11. (1)
- 12. Obesity Society. What is obesity? 2016, April. http://www.obesity.org/obesity/resources/facts-about-obesity/what-is-obesity. Retrieved 6/6/17.
- 13. (12)
- 14. (2)
- 15. (2)
- 16. Tsai, A.G., Williamson, D.F., & Glick, H.A. Direct medical cost of overweight and obesity in the USA: A quantitative systemic review. Obesity Review. 2011. 12; 50-61.
- 17. (4)
- 18. U.S. Department of Agriculture, Center for Nutrition Policy and Promotion. Estimated calorie needs per day by age, gender, and physical activity level. 2014. https://www.cnpp.usda.gov/sites/default/files/usda_food_patterns/ EstimatedCalorie NeedsPerDayTable.pdf. Retrieved 6/6/17.
- 19. Guth, E. Healthy weight loss. JAMA. 2014. 312; 924.
- 20. Swift, D. L, Johannsen, N. M., Lavie, C. J., Earnest, C.P., & Church, T.S. The role of exercise and physical activity in weight loss and maintenance. Progress in Cardiovascular Diseases. 2014. 56; 441-447.
- 21. DeMaria, E.J. Bariatric surgery for the morbid obesity. The New England Journal of Medicine. 2007. 356; 2176-2183.
- 22. Chang, S., Stoll, C.R.T., Song, J., Varela, E., Eagon, C.J., and Colditz, G.A. The effectiveness and risks of bariatric surgery: An updated systematic review and meta-analysis, 2003-2012. Journal of the American Medical Association Surgery. 2014. 149; 275-287.
- 23. Blanck, H.M., Serdula, M.K., Gillespie, C.G., Galuska, D.A., Sharpe, P.A., Conway, J.M., Kahn, L.K., & Ainsworth, B.E. Use of nonprescription dietary supplements for weight loss is common among Americans. Journal of the Academy of Nutrition and Dietetics. 2007. 107; 441-447.
- 24. U.S. Food and Drug Administration. Beware of products promising miracle weight loss. Consumer Update. https://www.fda.gov/ForConsumers/ ConsumerUpdates/ucm246742.htm. Retrieved 6/6/17.
- 25. Smith, T.J., SIgrist, L.D., Bathalon, G.P., McGraw, S., Karl, J.P., & Young, A.J. Efficacy of meal-replacement program for promoting blood lipid change and weight and body fat loss in US Army soldiers. Journal of the American Dietetic Association. 2010. 110; 268-273.
- 26. Lee, K., Lee, J., Bae, W.K., Choi, J.K., Kim, H.J., & Cho, B. Efficacy of low-calorie, partial meal replacement diet plans on weight and abdominal fat in obese subjects with metabolic syndrome: A double-blind, radomised controlled trial of two diet plans one high in protein and one nutritionally balanced. International Journal of Clinical Practice. 2009. 63; 195-201.
- 27. Davis, L.M., Coleman, C., Kiel, J., Rampolla, J., Hutchisen, T., Ford, L., Andersen, W.S., & Hanson-Mitola, A. Efficacy of a meal replacement diet plan compared to a food-based diet plan after a period of weight loss and weight maintenance: A randomized controlled trial. Nutrition Journal. 2010. 9; 1-10.
- 28. Noakes, M., Foster, P.R., Keogh, J.B., & Clifton, P.M. Meal replacements are as an effective as structured weight-loss diets for treating obesity in adults with features of metabolic syndrome. The Journal of Nutrition. 2004. 134; 1894-1899.

- 30. Johansson, K., Neovius, M, & Hemmingsson, E. Effects of anti-obesity drugs, diet, and exercise on weight-loss maintenance after a very-low-calorie diet or lowcalorie diet: A systematic review and meta-analysis of randomized controlled trials. American Journal of Clinical Nutrition. 2014. 99; 14-23.
- 31. (3)

32. (25)

- 33. König, D., Kookhan, S., Schaffner, D., Deibert, P. & Berg, A. A meal replacement regimen improves blood glucose levels in prediabetic healthy individuals with impaired fasting glucose. Nutrition. 2014. 30; 1306-1309.
- 34. (26)
- 35. (26)
- 36. (28)
- 37. (27)
- 38. Heymsfield, S.B., Harp, J.B., Reitman, M.L., Beetsch, J.W., Schoeller, D.A. Erondu, N., & Pietrobelli, A. Why do obese patients not lose more weight when treated with low-calorie diets? A mechanistic approach. American Journal of Clinical Nutrition, 2007. 85; 346-354.

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