

Effect of balanced low calorie meal replacement formula diet in the management of overweight/obesity and metabolic profile-a retrospective clinical experience report

Abstract

A balanced low calorie meal replacement (BLC-MR) formula diet has been indicated to manage overweight/obesity and metabolic profile of obese/overweight individuals, thus effectively support in reducing the economic burden of the disease and its consequences. The present retrospective clinical experience report enrolled 5 patients with type 2 diabetes mellitus with or without any medication for diabetes. The patients were requested to consume a BLC-MR formula diet for a period of 8 weeks by replacing their breakfast, lunch and dinner. In case they felt hungry at any time of the day during the study period, they were requested to consume cooked vegetables. On day 0 (week 1), measurements of body weight, body mass index, and body fat were performed. Fasting and post prandial blood sugar levels, serum insulin, HOMA-IR and HOMA $\beta\%$ were assessed. These measurements were repeated at end of week 8 after the intervention period was over. All measurements were undertaken using standard methodology. All patients were under strict monitoring of the practicing doctor. BLC-MR formula diet resulted in a significant reduction in body weight ($p=0.004$), body mass index ($p=0.0002$) as well as body fat percentage ($p=0.008$) among patients with diabetes. There were significant improvements in glycaemia showing reduction in fasting ($p=0.011$) and postprandial blood sugar levels ($p=0.012$). Serum insulin levels ($p=0.044$) significantly reduced. Significant improvements were also observed in insulin resistance (HOMA-IR; $p=0.029$) and β cell function (HOMA% β ; $p=0.008$). These results indicate that managing overweight/obesity through BLC-MR formula diet not only accomplishes its primary function of managing weight status, but also supports diabetes management. More studies with larger sample size are required to confirm the results.

Keywords: meal replacement, overweight/obesity, metabolic profile, *Garcinia*, green tea extract, conjugated linoleic acid, weight loss, hypertension, dietary management, lipolysis, body weight, glycated hemoglobin

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Nitin Patankar,¹ Neha Patankar,¹ Priyali Shah²

¹Wisdom Clinic, India

²Uth Healthcare, India

Correspondence: Nitin Patankar, Wisdom Clinic, Patel Building Room No. 3, mg Road, Mulund West, Mumbai-400 080, Maharashtra, India, Tel +91 9223145551, Email wisdomclinic@yahoo.in

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Abbreviations: VLCD, very low calorie diets; BLCMR, balanced low calorie meal replacement; BW, body weight; BMI, body mass index; FBG, fasting blood glucose; FSI, fasting serum insulin; PPBG, post prandial blood glucose; BF, body fat; WHR, waist hip ratio; HCA, (-)-hydroxycitric acid; CLA, conjugated linoleic acid

Introduction

Obesity continues to be a major worldwide problem, both in developed as well as resource poor nations. Diet plays an important role in the treatment of not only obesity but also related health conditions as diabetes, dyslipidemia, cardiovascular disease, and hypertension. Although dietary management is a difficult task, intensive lifestyle interventions can achieve weight loss that is sustained over the long term. Lifestyle interventions can be achieved by improving the quality of foods consumed and choosing healthy alternatives. Reports indicate high protein content foods provide better satiety and can support in the management of overweight/obesity. Evidences also suggest that rapid initial weight loss results in better long term weight loss maintenance.¹

In recent times, over nutrition, physical inactivity, and obesity are being highly recognized as major concerns among population at large affecting individuals in the pathogenesis of diabetes as well as other non-communicable diseases. Lifestyle intervention is recommended as a first line therapy for its management. And often lifestyle interventions fail to achieve or maintain goals either because of failure to lose weight, weight regain, progressive disease, or a combination of factors.

Meal replacement therapy is a way wherein foods consumed during the meal moments of the day (such as breakfast, lunch, dinner or snack times) are replaced by foods that are usually low in calorie content but have a balanced and healthy mix of carbohydrates, proteins and fats. Meal replacements are usually for weight management and thus also support disease management, particularly diabetes. Meal replacements make sure to provide all micronutrients (minerals and vitamins) daily required for the individuals.

Meal replacements by low calorie balanced meals have shown to improve weight management. A low carbohydrate and fat, and a high consumption of protein, allows reducing adipose tissue through

balancing the insulin-glucagon ratio in favor of lipolysis. The Very Low Calorie Diets (VLCDs) consist of a complete replacement of regular meals with food formulations that provide 400-800 calories per day.^{1,2} Recent data suggests that provision of meals and use of meal-replacement products promote greater weight loss.³ Excellent weight loss, reduction in fat mass, increase in lean mass, and improvement in metabolic parameters have been reported.⁴

The present patient care therapy was planned to evaluate the efficacy of a Balanced Low Calorie Meal Replacement (BLC-MR) formula diet on the improvement of weight status (Body Weight, Body Mass Index, Body Fat) and metabolic profile (fasting blood sugar, post prandial blood sugar, fasting insulin, HOMA-IR, HOMA β%) among overweight/obese patients with type 2 diabetes mellitus. The present retrospective clinical report shares experience on the therapy.

Methodology

Study design

The present pilot study was conducted at a diabetes clinic in Mumbai among patients with type 2 diabetes mellitus [inclusion criteria BMI ≥ 25 kg/m²; age > 18 years]. Patients were explained the dietary regimen (BLC-MR formula diet) to manage their overweight/obesity as well as diabetes condition by the attending physician. After a detailed discussion of the pros and cons of this dietary regimen, 5 patients were willing to undergo the care therapy. Any patient with dietary restrictions or undertaking any aggressive physical activity was not included. The patients continued with their specific medication and were monitored closely for the doses during the dietary care therapy.

Dietary intervention

The patients were provided with a BLC-MR formula diet (nutrition information as provided in Table 1) to be consumed by replacing the 3 major meals of the day i.e. breakfast, lunch, and dinner. Percent energy intake from carbohydrates, protein and fats due to the BLC-MR formula diet were 49.5, 45.2 and 5.3 percent, respectively. The patients were requested to reconstitute the BLC-MR formula diet by lukewarm water leading to an energy intake of approximately 85kcal per meal. Additionally, patients consumed cooked vegetables except tubers (potatoes, sweet potatoes, *arbi*, *jimikand*) in case they felt hungry at any time of the day during the patient dietary care therapy period. Patients were advised to avoid any sugary fruit during the dietary care therapy weeks. The total energy intake of the patients was 255kcal per day from BLC-MR formula diet and approximately 650kcal from cooked vegetables throughout the day. The total energy intake per day was 855kcal resulting in a balanced low calorie diet.

Clinical assessment

At enrollment (day 0), Body Weight (BW) and height was measured using standard method, subsequently Body Mass Index (BMI) was calculated. Weight was measured to the nearest kilograms and height to the nearest centimeters. The Body Mass Index (BMI) was calculated by using the formula weight (kg)/height (m)². Percentage of body fat was measured using the leg-to-leg bioelectrical impedance method (Tanita TBF 300; Tanita Corp, Tokyo, Japan). Biochemical parameters Fasting Blood Glucose [FBG], Post Prandial Blood Glucose [PPBG], Fasting Serum Insulin [FSI], Glycated Hemoglobin [HbA_{1c}] were measured utilizing standard methods. β-Cell function and insulin resistance were evaluated by calculating HOMA-β and HOMA-IR [Homeostasis Model], respectively by standard method.

Table 1 Nutrient composition of balanced low calorie meal replacement (BLC-MR) formula diet*

Nutrient composition	Approximate value per serving
Energy	85kcal
Carbohydrates	10.5g
Sugar	0g
Protein	9.6g
Fat	0.5g
Fiber	4g
Green Tea Extract (containing 30% polyphenols)	240mg
Hydroxycitric Acid Conjugated Linolenic Acid (CLA)	240mg
Vitamin C	21.6mg
Inositol	72mg
Vitamin E	3.6mg
Nicotinamide	12mg
Pantothenic acid	0.9mg
Vitamin B ₆	0.36mg
Vitamin B ₁	0.9mg
Vitamin B ₂	0.9mg
Vitamin A	540μg
Folic Acid	42μg
Biotin	18μg
Vitamin D	2.25μg
Vitamin B ₁₂	0.45μg
Chloride	270mg
Potassium	234mg
Calcium	201mg
Magnesium	120mg
Phosphorus	100mg
Sodium	90mg
Iron	8mg
Zinc	4.5mg
Manganese	2.3mg
Copper	0.9mg
Chromium	35μg
Iodine	90μg
Selenium	55μg
Molybdenum	30μg
Vanadium	12μg

Dietary assessment

Energy intake of the patients was assessed at the time of enrollment utilizing the standard 24-hour dietary recall method by the practicing dietician at the clinic.

All dietary and clinical measurements and investigations were repeated after the end of the dietary regimen (end of week 8). Telephonic monitoring of the enrolled patients was planned biweekly for any adverse effects due to the dietary regimen and in regards to compliance. All dietary intakes were also closely monitored among the enrolled subjects by the dietician at the clinic. All medicinal intakes of the patients were recorded and dosages carefully monitored by the attending physician.

Statistical analysis

All data was entered in Microsoft excel sheet and carefully checked for any typographical errors. Data was analyzed by Fisher's exact test and statistical significance between time points was calculated by Student's T test. Efficacy of the BLC-MR formula diet was estimated by significant decrease in BW, BMI, BF, FBG and PPBG levels, FSI, and HOMA-IR at end of the intervention period. Significant

increase in HOMA $\beta\%$ was also an indicator of efficacy of the BLC-MR formula diet for improvement in metabolic profile. Side effects/adverse events, if any, were reported.

Results

Three males and two females type 2 diabetes patients with duration of onset of diabetes in the range of 1-12years participated in the study. The age range of the patients was 26-61years with less than 40minutes of daily physical activity such as walking. Four of the five patients were daily receiving oral hypoglycemic drugs. The total daily energy intake before intervention ranged from 1400kcal to 2200kcal. All the patients were vegetarians.

The mean baseline and post intervention anthropometric measurements and metabolic parameters of the study subjects in shown in Table 2. On an average, there was a 9.6kg weight reduction among the patients over the diet therapy duration ($p=0.000$). BMI and BF significantly reduced by 3.6kg/m² and 7.6%, respectively, during this period ($p=0.000$, and $p=0.008$, respectively). Intake of BLC-MR formula diet intervention for a period of 8weeks resulted in significant improvement in all investigated parameters of anthropometric measurements as well as metabolic profile (Table 2).

Table 2 Mean (SD) anthropometric measurements and glucometabolic profile of the study subjects before and after intervention by BLC-MR formula diet

Parameter	At baseline	At end of intervention	p value*
Anthropometric measurements			
Body weight (kg)	79.4±10.1	69.8±10.0	0.004
Body Mass Index (kg/m ²)	29.6±2.3	26.0±2.7	0.0002
Body Fat %	37.9±5.9	30.3±4.3	0.0085
Metabolic profile			
Fasting Blood Glucose [FBG] (mg/dl)	162.4±31.0	89.4±7.9	0.011
Post Prandial Blood Glucose [PPBG] (mg/dl)	244.4±53.9	122.0±17.1	0.012
Glycated Hemoglobin [HbA _{1c}] (%)	8.9	6.6	0.01
Fasting Serum Insulin [FSI] (micro IU/ml)	29.3±10.9	14.1±1.3	0.044
HOMA-IR	4.1±1.4	1.8±0.1	0.029
HOMA- $\beta\%$	88.9±42.1	148.4±27.2	0.008

*Obicure Powder

*p values<0.05 were considered as significant

Discussion

This study demonstrates that patients with type 2 diabetes on any of the medical therapy to control their metabolic profile were able to improve their metabolic parameters by a BLC-MR formula diet in 8weeks. Significant improvements were observed in their anthropometric measurements. Subjects with overweight/obesity improved in their weight status and moved to an overweight condition. Patients with a high fasting blood glucose level indicative of diabetes (FBG \geq 126mg/dl) improved to either no diabetes or pre-diabetes condition. The dosage of medicines reduced to no medicine or low dose medicine as per their metabolic profile, implicating reversal of the diabetes condition.

Lifestyle management (dietary intake control and improved physical activity) should be the main driver for improving

anthropometric measurements as well as metabolic profile of patients with diabetes. A review of various studies has shown that a daily diet with a deficit of 500-1000kcal per day will lead to on an average weight loss of between 0.3 and 1kg per week, depending on the patient's initial weight.⁵ Other studies have indicated that low calorie diets with balanced ratios of carbohydrates, proteins and fat can lead to a weight loss of as high as 10kg in subjects with higher initial weight.⁶

Another study with intensive energy intake restriction (800kcal/day) diet for a 12week period resulted in significant improvement in Body Mass Index and HbA_{1c} levels. The study recommended intensive energy restriction among obese type 2 diabetic patients for improvement in obesity status as well as metabolic profile.⁷ Another study with protein enriched energy restricted meal replacement diet showed significant improvements in HbA_{1c} levels along with improvements in anthropometric measurements such as Body Weight,

Body Mass Index, and Waist Hip Ratio. The study also showed significant improvements in the glycaemia with reduction in fasting blood glucose levels, triglycerides as well as improvements in the high density lipoprotein levels. Overall in the study subjects, there was a reduction in the insulin dose after an intervention of a 12week period.⁸

In a recent trial, obese patients were administered a series of meal replacement therapy. The first 30days were 4-5 meal replacements with very low calorie diets (700kcal/day) followed by 30days of low calorie diets (3 meal replacements+1 protein dish; 820kcal/day), next 60days of 1100kcal/day diet (2 meal replacements+2 protein dishes+reintroduction of small amounts of carbohydrates) followed by another 60days of 1250kcal/day dietary regimen (1 meal replacement+2 protein dish+complete reintroduction of carbohydrates). This intensive stage wise meal replacement therapy resulted in significant weight loss and a fat mass reduction. Glucose, insulin, triglycerides, and total cholesterol, showed a statistically significant progressive reduction. The reductions in fasting glucose and insulin caused a significant improvement in the HOMA-IR, similar to the present study.

These studies have been conducted over a 12week period or a longer duration as compared to the present dietary therapy duration. We believe a strict balanced low calorie dietary regimen for a short period of time is successful in significantly improving the anthropometric measurements as well as the metabolic profile of the overweight/obese patients with type 2 diabetes. Although the HbA_{1c} is an indicator of average blood glucose levels over a longer period of time (at least 3month), this patient care therapy shows that even in short duration of intensive lifestyle intervention, there are significant improvements in the metabolic profiles.

The BLC-MR formula diet used in the current pilot study also contained active bio ingredients (*Garcinia cambogia*, green tea extract and conjugated linoleic acid) that have been reported to be supporting improvement in the weight status.

(-)-Hydroxycitric acid (HCA) is an active ingredient extracted from the peel of the Indian fruit *Garcinia cambogia*. It is a competitive inhibitor of Adenosine Triphosphate Citrate Lyase⁹⁻¹¹ the enzyme that catalyzes the extra mitochondrial cleavage of citrate to oxaloacetate and acetyl coenzyme A. This action of HCA reduces the acetyl coenzyme A pool, thus limiting the availability of 2-carbon units required for fatty acid and cholesterol biosynthesis.¹² Studies show that HCA inhibits the actions of citrate cleavage enzyme, suppresses the fatty acid synthesis, increases rates of hepatic glycogen synthesis, and decreases body weight gain.¹³⁻¹⁷ An intervention of 2.4 g *Garcinia cambogia* for 12week period among overweight females.¹⁸ Resulted in significant weight loss compared to the placebo group (3.7±3.1kg versus 2.4±2.9kg). When *Garcinia cambogia* extract (500mg) was given 3times a day for a 8week period, individuals lost on an average of 5.1kg/person while those in the control group lost an average of 1.9kg/person¹⁹ Similar results were reported in another study.²⁰ Thus, *Garcinia cambogia* derived (-)-Hydroxycitric Acid (HCA) is a safe, natural supplement for weight management.²¹

Conjugated Linoleic Acid (CLA) refers to a group of positional and geometric isomers of linoleic acid that are characterized by the presence of conjugated dienes²² and reported to have benefits as body fat reduction. CLA is a natural, but minor, component of fats from ruminant animals that enters the human diet primarily in meat

and dairy products. CLA has been shown to have many biological effects, including anti-carcinogenesis, anti-atherogenesis, immune modulation, and changes in body composition. Many studies have investigated the effect of CLA on body composition, and most find that CLA reduces body fat. It has also been found that CLA decrease and reverse atherosclerosis as well as increase insulin resistance. (Supplementation of CLA for 12week in overweight and Grade I obese Chinese subjects resulted in lower obesity indices, with no obvious adverse effects.²³

Green tea catechins have been suggested to have anti-obesity effects. The ingredients in green tea play a role in increasing energy metabolism, resulting in weight loss.²⁴ In a randomized controlled study, intake of high catechins green tea (468mg catechins) by moderately overweight Chinese subjects for a period of 90days lead to reduction in intra-abdominal fat, waist circumference reduction, reduction in body weight, total body fat and body fat % indicating improvements in body composition and reduction in abdominal fatness.²⁵ Another 12week study from Japan among men and women with increased visceral adiposity, consumption of a beverage providing 583mg/d of tea catechins were associated with significantly greater reductions in body weight, body fat, and abdominal fat mass compared with a control beverage providing 96mg/d.²⁶

The source of protein in BLC-MR formula diet was whey protein. Research shows positive effect of dairy proteins on markers of diabetes.²⁷ Specific to dairy proteins, whey protein has reached popularity because it has been suggested as a strategy for the prevention and treatment of obesity and diabetes. Evidence suggests whey protein to support higher satiety thus a reduction in food intake due to increased release of gut hormones cholecystokinin, leptin and GLP-1 as well as a decreased release of the hunger hormone ghrelin. Furthermore, whey protein also supports the reduction of inflammatory and oxidative stress markers along with reduction of blood pressure.²⁸ Whey protein is a rich source of essential and branched chain amino acids (leucine, isoleucine and valine) that are known to have potential insulinotropic properties²⁹ and are potential modulators of glycemia. Intake of whey protein also maintained postprandial glycemia more stable. Compared to vegetable protein, whey protein was capable of avoiding great fluctuations and a peak in postprandial glycemia.³⁰ Results from our study demonstrate that a tight control on energy intake with a whey protein intake along with a regular physical activity is effective in improving the metabolic profile of patients with type 2 diabetes mellitus.

Overall, it is clear that a balanced low calorie meal replacer formula diet with the added benefits of natural bio-actives supports weight reduction as well as improved metabolic profile, subsequently supporting health care professionals in the management of the disease condition (specifically diabetes). Careful and strict monitoring of the intervention can support and encourage patients in continuing their intensive dietary regimen. The present study was a pilot study. More studies with larger sample size are required to confirm the results of the present study.

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None.

Conflict of interest

The author declares no conflict of interest.

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