

FORMULA DIETS: EVIDENCE REVIEW

Discussions at the symposium organised by Cambridge Weight Plan during the 13th International Congress of Obesity in Kuala Lumpur, March 2014.

Margaret Ashwell, Pia Christenson, Winnie Chee, Michael Lean and Anthony Leeds

Dr Margaret Ashwell (Ashwell Associates, chair) introduced the symposium by showing data about the worldwide pandemic of obesity and stressing the enormous costs to society that are posed by people with BMIs greater than 40. Direct costs are doubled, whilst indirect costs (such as that from absenteeism) are multiplied eight-fold. While obesity statistics are always expressed in terms of BMI, she reminded everyone that a simpler way to screen for health risks would be to use the waist-to-height ratio and to adopt the simple message, 'Keep your waist to less than half your height'.

VLCDs AND LCDs

Professor Anthony Leeds (Medical Director, Cambridge Weight Plan) discussed the mechanism of action of very low calorie diets VLCDs (below 800kcal/d - sometimes 400-500kcal/d), low calorie diets (LCDs), i.e. part-food and part-formula (800kcal/d and above) and total diet replacements (TDRs, 800kcal/d). They all create a large energy deficit in comparison to a normal reducing diet, which means that they produce greater weight losses, linked to better weight maintenance. Further, they facilitate portion control, especially for people who have difficulty with self-selection; the lower calorie diets also probably help appetite suppression through the effects of ketosis. Adverse event profiles for VLCD and LCD have been fully and openly defined and the published losses of lean body mass have been less than expected.

Professor Leeds considered, 'Is it possible to define the amount of weight

loss needed to achieve a given effect?'. He concluded, from a strong evidence base, that a weight loss of 15kg was ample to prevent pre-operative 'liver shrinkage', and adequate for a reduction in symptoms of obstructive sleep apnoea, to reverse insulin resistance in diabetes, to reduce inflammation in the skin in psoriasis and to reduce pain scores in osteoarthritis.

An important use for VLCDs and LCDs is their ability to produce a rapid weight loss or support weight maintenance with other methods such as anti-obesity drugs, high protein diets and exercise. A recent systematic review and meta-analysis by Johansson and colleagues (2013), included 20 studies with a total of 27 study arms and 3,017 subjects. Figure 1 shows that the VLCD/LCD period, mean duration eight weeks, produced a pooled weight loss of 12.3kg. Trials using meal replacements after the rapid phase showed the best long-term results. About 13kg weight loss was maintained at 18 months. The thick lines represent the active intervention and the thin lines represent the control group in each category. There was a 3.9kg difference between the meal replacement intervention group and its corresponding control group. ($p=0.01$).

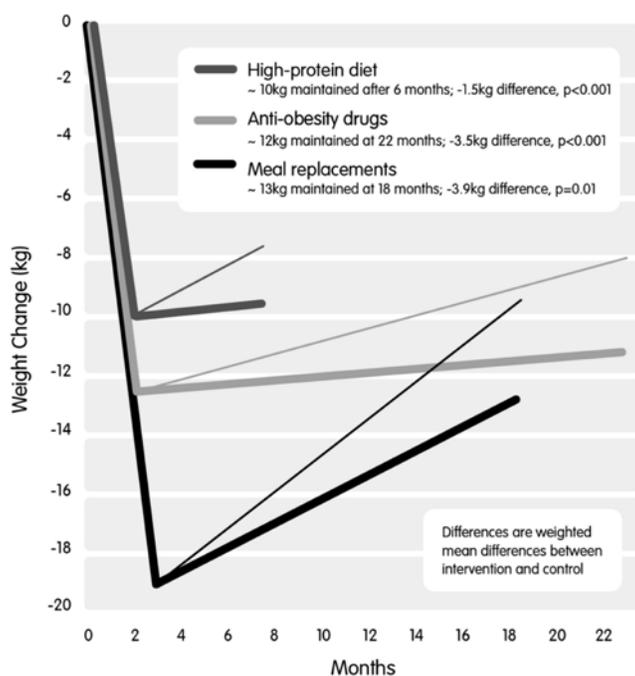
IMPROVING NUTRITIONAL STATUS WHILE LOSING WEIGHT WITH FORMULA DIET

Obese subjects often exhibit poor micronutrient status. This maybe because they eat a diet of poor quality, they have alterations in metabolic processes and/or they have increased physiological requirements. Weight loss may actually worsen this status and cause deficiencies.

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Figure 1

Body weight change during the VLCD or LCD period followed by the weight loss maintenance period. The thin lines represent the control subjects in each category, while the thick lines represent the active intervention.



Redrawn from Effects of anti-obesity drugs, diet and exercise on weight loss maintenance after a very low-calorie diet or low-calorie diet: a systematic review and meta-analysis of randomised controlled trials Johansson K, Neovius M, Hemmingsson E Am J Clin Nutr 2013 published online 30 October 2013.

Dr Pia Christensen, Clinical Dietitian at the University of Copenhagen, presented the results from a very long-term study to see how nutritional status of vitamin D, vitamin B12 and ferritin, are affected by a formula diet intervention. These diets must, by legislation, provide 100 percent of the recommended daily intake of vitamins and minerals and might therefore help to improve nutritional status.

A cohort of 192 sedentary obese knee osteoarthritis patients were followed over 68 weeks. Initially, they were asked to use a very low calorie diet (VLCD) or a low energy diet (LCD) for eight weeks, followed by a fixed energy diet period of another eight weeks, eating approximately 1,200kcal/day including two formula products. At baseline, 48 percent of the participants had poor vitamin D status and 19 percent had poor vitamin B12 status. However, ferritin was not

an issue in this population. After 16 weeks, when weight loss was on average 14kg, significant increases were seen in both vitamin D and vitamin B12 status; ferritin was unchanged.

After the first 16 weeks of dietary intervention, participants were assigned to one of three subsequent treatment groups with an equal allocation ratio (1:1:1) to diet, exercise or control. At the end of 68 weeks, the beneficial effects were maintained. Vitamin D status had increased in all groups, but significantly more so in the diet group. The improvement in vitamin B12 was maintained in all groups with no difference between groups. Ferritin was unchanged and not different between groups. There was a small drop in bone mineral content in all three intervention groups with no difference between the groups, and there was no change in bone mineral density in any of the groups.

Professor Winnie Chee, Dept of Nutrition & Dietetics, International Medical University, in Kuala Lumpur, spoke about weight loss with formula diet in Malaysia. There was a rising rate of overweight/obesity in Malaysia which imposed massive

burdens of ill health, especially Type 2 Diabetes Mellitus (T2DM). However, the medical consequences of obesity can be alleviated by modest, achievable weight loss of five to 10 percent. Formula diets are now widely available to consumers in Malaysia and their use does not always involve medical supervision.

A few local studies have shown weight loss and metabolic benefits in using formula diet as partial meal replacements. She observed that, although VLCDs produce weight loss and are effective ways to combat obesity, the use of formula diets in the Malaysian environment poses similar challenges to any other dietary weight loss prescription. Challenges include the fact that calorie-laden foods are easily accessible, travels and holidays pose difficulties with structured eating and there are sometimes family and social commitments which reduce adherence to the plan. All

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too often, cravings, hunger and boredom can ruin motivation. In addition, the milk-based formula diets, are not always well suited to Malaysian taste buds which are accustomed to spicy and rice-based staple foods. Furthermore, they may be more costly than eating standard meals.

REVERSING T2DM WITH LOW-CALORIE FORMULA DIETS

Professor Mike Lean, Professor of Human Nutrition, University of Glasgow, spoke on the topic of 'Reversing T2DM with low-calorie formula diets'. This disease now affects five to 10 percent of adults in different countries, and its prevalence is rising in parallel with that of obesity. This indicates that T2DM is preventable by avoiding weight gain and potentially reversible by weight loss at an early enough stage.

Life expectancy for those with T2DM is reduced by six to eight years even if current clinical management guidelines are followed - often five to six different drugs daily. Patients might reduce their cardiovascular risks by a maximum of 15 percent (leaving 85 percent of the excess risks), but T2DM still brings a catalogue of disastrous complications, including blindness, leg ulcers and amputations, intractable neuropathic pain, impotence, recurrent infections, strokes and heart failure.

The focus on glucose-lowering for patients with T2DM ignored the underlying cause - the weight gain. Attention has, therefore, turned away from controlling blood glucose and onto controlling the obesity. The Scottish SIGN Guideline of 2010 was the first to declare a weight loss of 15kg or more as a new target for treating patients with obesity complicated by T2DM. This figure was derived from several sources including Professor Lean's own study published in 1990 which showed that, to normalise life-expectancy in T2DM patients, the weight loss had to be over 15kg. Weight management with VLCDs and LCDs may be able to normalise glucose tolerance and to reduce many other co-morbidities for large numbers of T2DM patients.

A NEW TRIAL

The Diabetes REmission Clinical Trial (DiRECT) will explore whether a structured long-term weight management programme using LCDs could be applied economically and effectively in a primary care setting. If successful, it would establish a new paradigm for the treatment of T2DM, i.e. to achieve a remission of T2DM and its complications without the need for drugs or surgery. DiRECT will recruit and randomise practices in North-East England and Scotland during 2014. Intervention practices will receive the Counterweight-Plus programme with an 820kcal/day formula diet for 12 weeks, followed by a structured, but flexible, food-re-introduction and weight maintenance programme delivered by trained staff. The control practices will continue to provide normal diabetes care according to current clinical guidelines.

The results will not be available for about four years, but Professor Lean was excited about the published pilot data. The Counterweight Feasibility study showed that 33 percent of severely obese non-diabetic patients could maintain a weight loss of more than 15kg at 12 months, using an 820kcal/day formula diet, with structured dietary and exercise support for maintenance. The figure among diabetic patients currently using Counterweight-Plus in primary care is similar, or better.

It, therefore, appears that a 15kg weight loss can remove the pathological basis for diabetes development and normalise metabolism. Further, the treatment might be deliverable, in a primary care setting, at a fraction of the cost of bariatric surgery. However, Professor Lean stressed that they still only have data up to 12 months and only a few cases of T2DM have been studied. DiRECT will also assess possible stress and disruption for patients and their families and disappointment for those who simply cannot adhere to a tough dietary restriction. The DiRECT study has therefore been designed to test whether long-term weight management with formula diets can justify a radical change in the management of diabetes. ■