

Position Statement on Very Low Energy Diets in the Management of Obesity

Introduction

Very low energy diets [VLED] are perhaps the most controversial of the various dietary treatments available for use in the management of obesity. This seems to relate mainly to concerns over their safety and long term efficacy. This paper aims to summarise the evidence on the use of VLED in the management of obesity, to highlight areas of uncertainty in the literature and discuss how this relates to their use in practice.

Definition

VLED are defined according to the international CODEX standardisation and legislation by the US Food and Drugs Administration and European Union as total diet replacements with an energy content <800kcal and >450kcal/day^{1,2}.

Although this is the classic definition, VLED also share a number of other key features as outlined below.

- Complete substitution of all usual food intake: Traditionally VLED are liquid formulations consumed to the exclusion of usual food however there are some less frequently used food based versions. However the main body of research and hence most of the conclusions drawn in the literature, and this position statement, relate to liquid formulations
- VLED are used as the sole source of nutrition: As such there is a requirement for a full complement of vitamins, minerals, electrolytes and fatty acids to be included in liquid formulations¹. Food based VLED will necessitate separate vitamin and mineral supplementation
- VLED are usually given over a 12-16 week period^{3,4} although recent guidance suggests continuous use should not extend beyond 12 weeks⁵.

It is important that VLED are not confused with meal replacements which are used to replace one or two meals per day and should not be used as a sole source of nutrition [see DOM UK meal replacement position statement for further details of this strategy].

History

VLED were first devised in the 1920's to elicit large rapid weight losses without the associated dangers of total starvation. The emergence in the 1970's of the protein sparing modified fast, a food based high protein approach providing 650-800kcal per day, increased interest in the use of VLED⁶. This approach was later modified to liquid formula preparations. However some of these early formulas contained low biological value protein having been produced primarily from collagen sources. This low quality and quantity of protein together with inadequate supplementation of vitamins, minerals and electrolytes was believed to be associated with, although no direct link was made, to cardiac dysrhythmias and a number of sudden unexpected deaths in the late 1970s. There was a subsequent overhaul of the preparations with recommendations for a defined period for usage and the need for close medical supervision. No such associations have been observed since these modifications were implemented⁷.

In the early days of VLED use greater emphasis was given to diets at the more extreme end of the energy restriction range [i.e. closer to 400kcal/day] however research has demonstrated no improvements in weight loss over 12 to 16 weeks at this more extreme energy restriction^{8,9}.

Efficacy of Weight Loss and Weight Maintenance

In theory VLED should, if used as guided, produce substantially greater and quicker weight loss compared to low calorie diets. Some studies do indicate that in the short term VLED can produce weight losses in the region of 9-26kg^{10,11,12}. As VLED tend not to take account of differences in energy requirements, variations in weight loss can be observed between groups, for example, men and women: women may lose ~1.5kg/wk and men ~2kg/week³.

The important question in relation to efficacy is whether VLED lead to greater weight loss over the longer term compared to conventional diets and this is where difficulties arise in drawing conclusions from the available research.

There is no clear consensus on what is defined as long term. In addition there are variations in how studies calculate long term success together with numerous variations in study design [treatment type, length of treatment, follow up support] that make comparisons across studies challenging. However, Saris (2001) in his paper on VLED and sustained weight loss identified 9 RCTs, with only two of these reporting weight changes over five years¹³. Both of the five year studies

included behaviour therapy, however remarkable differences were observed between weight regain percentages, with complete regain in one study¹⁴, compared with only 26% regain in the second¹⁵. The precise reasons for such variations remain unclear. In the NIH clinical guidelines four RCT's were identified comparing VLED of 400-500kcal/day with low calorie diets of 1000-1500kcal/day for a period of 6 months to 5 years. Although the VLED produced greater initial weight loss, after 1 year VLED were no more effective than the more conventional dietary treatment¹²

There is some evidence to support the notion that VLED suit some individuals but not others. In studies using VLED as part of comprehensive clinical trials approximately 25-35% of subjects managed to maintain a clinically significant weight loss of ~10% over 2-7 years^{16,17,18} but the majority of participants return to their pre-treatment weight.

The challenge in relation to weight maintenance begins during the reintroduction of 'normal' food after completion of the total replacement period. This reintroduction, which usually occurs over a 6-8 week period, is important in the development of knowledge and skills for food related changes and requires close support and monitoring.

Several randomised controlled trials suggest that weight maintenance is improved by using VLED as part of a comprehensive weight management programme including behaviour modification and/or drug therapy as part of follow up¹⁹.

Efficacy of VLED Use in Type 2 Diabetes

Weight management is the cornerstone of treatment in type 2 diabetes but is known to be particularly challenging. This has led to suggestions that more aggressive weight management interventions, including VLED, may have a potential role to play in managing obesity in those with type 2 diabetes.

At first sight a few individual studies have seemed promising. One such study compared a low calorie diet with intermittent VLED use and resulted in 14.2kg weight loss at one year in the VLED group compared to 7.2kg in the control group. However after 2 years weight loss was similar in both groups suggesting greater weight regain in the VLED group²⁰. This has led some to question whether the short term benefits of this approach can be justified against the longer term costs²¹.

This trend of greater initial weight loss and improved glycaemic control followed by accelerated weight regain has been observed in other studies. One 5 year study using intensive group treatment with or without VLED found slower but better maintained weight loss in the conventional dietary group²².

A recent Cochrane systematic review, which explored long term non-pharmacological weight loss interventions in type 2 diabetes, found VLED were no more effective over the longer term than low calorie diets²³. This is in line with an earlier review which found no difference in outcome between low calorie and VLED beyond a one year follow up²⁴.

Safety Aspects

Associated Side Effects

Minor: These side effects tend to be temporarily associated with the use of VLED and include dry mouth, constipation or diarrhoea, headache, dizziness, nausea, cramps, fatigue, hunger, feeling cold and hair thinning.

Serious: More severe adverse events include acute gout, cholelithiasis and acute psychosis. Cholelithiasis is a well known problem associated with obesity and the risk is increased with all forms of weight loss. The risk associated with the use of VLED may be lowered by the inclusion of a minimum fat content in formulations of 7g per day².

Indications for Use:

VLED should not be considered as a first line dietary treatment but may be considered where more conventional dietary and lifestyle modification approaches have proved unsuccessful plus a:

- BMI $\geq 30\text{kg/m}^2$
- BMI $\geq 30\text{kg/m}^2$ and a medical condition that would benefit from rapid weight loss e.g. severe obstructive sleep apnoea, prior to orthopaedic surgery

Contra-Indications to Use:

There are certain population groups and medical conditions in which the use of VLED is not advisable. These include:

- Infants and children
- Adolescents
- Pregnant and lactating women
- Elderly
- Unstable cardiac or cerebrovascular disease
- Acute and chronic renal failure
- Severe or end stage liver failure
- Acute psychiatric disorder

Duration of Use

Currently NICE recommends that VLED may be used continuously for no more than 12 weeks or intermittently with a low calorie diet [e.g. 2-4 days a week] in obese people who have reached a weight loss plateau⁵. However additional research would be valuable to understand the optimal duration of use and its influence on long term weight management.

Reputed Problems and Related Evidence

- *VLED and body composition changes*

Controversy remains regarding the composition of weight lost using VLED with some suggesting this approach may be associated with an excessive loss of lean tissue. Unfortunately there are various shortfalls in the evidence exploring body composition changes and there is an ongoing need for a more detailed understanding of such changes.

In an analysis of studies that had suggested loss of lean tissue was above acceptable levels, particularly where energy intake was below 440kcal/day[1.84MJ/day], a large number of studies were found to have used inadequate methodologies for the measurement of body composition often using prediction rather than reference methods. In addition the duration of these studies varied considerably with some body composition measurements being taken in the early stages of weight loss where greater loss of lean tissue is known to occur compared to later stages where metabolic adaptation is more established²⁵.

In one study in which reference methods were used to assess changes in body composition before and after 11 weeks of a 405kcal/day VLED the composition of lost weight was along the lines of the expected 75% fat 25% lean ratio²⁶.

There has been some suggestion that factors influencing lean and fat tissue losses may be specific to each individual and this may need to be considered in treatment outcomes²⁷.

- *VLED and resting metabolic rate*

A common concern associated with VLED use is whether there is an adaptive decrease in energy requirements resulting in weight losses below those that would be predicted with such a substantial energy restriction.

It is well established that a negative energy balance is associated with various physiological mechanisms that result in increased metabolic efficiency & reduced energy requirements. However the effect of 'dieting' on RMR may be less than commonly assumed by many lay people with an approximate 5% fall on diets of 1200kcal/day and 15% on diets of less than 700kcal/day²⁸. Although a decline in RMR is observed with implications for energy requirements it has been suggested this is probably not the explanation for difficulties with weight control and is more likely related to issues of dietary compliance²⁵.

An extension of this concern is whether metabolic rate is irreversibly depressed in the post obese state and whether this might be an explanation for the weight cycling commonly observed. Currently there is little evidence to support this theory although there are limited studies that have specifically explored this issue. One study that experimentally created yo-yo dieting through intermittent VLED use found that acute suppression of RMR during the 'dieting' phase was temporary with no significant decline in RMR at the end of the study despite a 6kg weight loss²⁹.

Other researchers have likewise suggested that once weight stabilises the RMR will be associated with the 'new' weight of the individual and their fat free mass^{26,28}. Other more general studies also suggest that weight cycling and yo-yo dieting does not adversely influence body composition or metabolic rate as previously suspected^{30,31}.

Conclusion

- VLED should not be used as a first line treatment and should be reserved for use in those with BMI $\geq 30\text{kg/m}^2$
- VLED may be useful for rapid weight loss in carefully selected obese people particularly where medical conditions would benefit from rapid weight loss.
- VLED must be used as part of a comprehensive management package with substantial focus on weight maintenance strategies following reintroduction of food.
- VLED should not be used for extended periods with continuous use limited to a 12 week treatment period
- Close medical and dietary supervision by experienced and well qualified health professionals is essential

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