White Paper

Obesity and Diabetes: Growing Epidemics

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At a time when pandemics and the opioid crises have become headline news, many health issues that impact vast segments of the population are virtually ignored. Epidemics such as smoking and obesity, which each are responsible for around 500,000 deaths each year,[1] [2] [3] are, at best, intermittently acknowledged with an occasional public service campaign. However, public health funding has declined steadily for more than two decades despite the positive impact of many medical and public health programs.[4] With little hope for national-level intervention, the responsibility for treatment remains in the hands of physicians and health care systems.

Obesity is associated with five of the top 10 preventable causes of death[5] and is both an national and global health issue, with nearly 40 percent of the adult population in the United States having a body mass index (BMI) over 30 kg/m^2.[6] Further, since nearly 20 percent of young people between the ages of six and 19 having obesity,[7] the number of people requiring treatment is on target to grow exponentially with little chance of reversal.

OBESITY-RELATED DIABETES

Chronic overweight and obesity contribute to a host of diseases and health conditions including several types of cancer, osteoarthritis, ischemic heart disease, hypertension, stroke, dyslipidemia, and more.[8] Perhaps the most prevalent – and preventable – health risk associated with obesity is diabetes. The link between obesity and diabetes is incontrovertible, with 90 percent of type 2 diabetes being overweight or obese.[9] More than nine percent of the American population — over 30 million people — have been diagnosed with diabetes,[10] and that number is expected to increase by 54 percent by 2030.[11] When pre-diabetics are counted, the number soars to over 100 million people.[12]

Those who are overweight or obese and not physically active are more likely to develop type 2 diabetes. This puts them at risk for further health complications including neuropathy, nephropathy, retinopathy, ketoacidosis and ketones, gastroparesis, foot and skin complications, depression, and hyperosmolar hyperglycemic nonketotic syndrome.[13] Because obesity causes some degree of insulin resistance, as well as heart and blood vessel disease,[14] type 2 diabetes can go undiagnosed for many years while hyperglycemia gradually develops. So, while patients may have insulin levels that appear normal or elevated, the higher blood glucose levels in these diabetic patients would be expected to result in even higher insulin values if their B-cell function was normal. However, insulin secretion is defective in these patients and insufficient to compensate for insulin resistance.

People with obesity also are more likely to have a preventable, premature death.[15] For every five units of BMI above 25 kg/m^2 , mortality risk is 31 percent higher[16] and the lives of adults with extreme obesity — BMI over 40 kg/m^2 — can be shortened by as much as seven to 14 years.[17] Additional risks of mortality are associated with cardiovascular disease (49 percent), respiratory disease (38 percent), and cancer (19 percent).[18] Fortunately, a converse relationship also exists, such that diabetic patients with obesity who lose 9-13 kg can reduce all-cause mortality by 25 percent.[19] Prevention and effective treatment are critical to close this gap.

There are also psychological and financial burdens. Direct costs associated with obesity-related chronic diseases are in the range of $480 billion,[20] and the costs to care for diagnosed diabetics represents 25 percent of health care dollars, around $237 billion.[21] Other diseases that affect the same number of people, result in a staggering number of deaths, or incur such exorbitant costs would instigate immediate action. However, in the absence of any such intervention, medical providers and health care systems will bear the burden of the physical, psychological, and economic impact of treatment.

EFFECTIVE WEIGHT LOSS TREATMENT

Weight loss and lifestyle change are critical to reducing and reversing type 2 diabetes. In the past 10 years, research on the use of Very Low Calorie Diet (VLCD) for this purpose has been growing. There has been clear support for the use of a VLCD as a key, successful component of an effective weight loss program that offers both physical and psychological benefits to improve health and quality of life. Findings from well-known studies such as Look AHEAD (Action for Health in Diabetes) and Diabetes Remission Clinical Trial (DiRECT) firmly established the benefits of weight loss from VLCDs for people with obesity and diabetes. Using meal replacements and other lifestyle interventions, participants experienced significant beneficial changes not only in weight loss, but also through improved lipids and glucose biomarkers, improved blood pressure, and reduced need for diabetes medication. Importantly, patients also experienced an improved quality of life and lower levels of depression. [22] [23]

More recent studies continue to confirm these findings across populations, including patients with obesity and diabetes. Multiple studies and reviews support the use of medically supervised meal replacement and VLCD programs as safe and effective for patients with obesity and diabetes, as summarized in Table 1.

For example, in a study of 29 diabetic VLCD users who discontinued their antidiabetic medications, 12 “responders” achieved normal fasting plasma glucose levels (<7mmol/L) after returning to the isocaloric diet, and 13 were normoglycemic at six months. They also had a higher initial fasting plasma insulin level.[24] Goday et al. had similar findings using a very low-calorie-ketogenic weight loss program. The reduction in weight, waist circumference, HbA1c and glycemic control was significantly greater in the intervention group suggesting that it was effective and well-tolerated by participants.

Weight loss among diabetic patients who receive insulin therapy typically is more challenging, though VLCDs also have been shown to be effective for this group. In van Wyk and Daniel’s study, patients with long-term diabetes who used VLCDs showed reduction in weight, waist circumference, BMI, fasting blood glucose, and pre-lunch and pre-dinner glucose. The change to blood glucose levels are important because the participants had long-term diabetes (15+ years) and reduced insulin use by 43 percent.[25]

Another recent (2020) study found the intervention group using total diet replacement lost more weight from fat mass than the control group, and their glycated hemoglobin fell significantly. They also discontinued insulin therapy at a higher rate (39.4 percent vs 5.6 percent) and by a greater amount (47.3 units v. 33.3. units), suggesting VLCDs are a safe treatment for insulin dependent patients.[26] Arguello et al’s study included patients with pre-diabetes and found that both groups benefitted from a VLCD, with significant reduction in diabetic medications, hypertension, and lipid control. Additionally, patients with pre-diabetes lowered their HbA1c to a normal range (<5.7 percent), indicating that VLCDs are also effective in preventing diabetes.[27]

No weight loss method is perfect and weight regain is common. However, because VLCDs are high in protein, they increase satiety, which makes it easier for patients who may become frustrated by hunger to adhere to the program. This leads to reduced glycaemia which offers near immediate health improvements for diabetics. As such, VLCDs are a desired option because rapid weight loss, particularly during the initial phases of dieting, is highly gratifying to patients,[28] which increases motivation and enthusiasm[29] and leads to greater, long-term weight management.

MOVING FORWARD

More than 1.6 million people in the United States are diagnosed with diabetes each year, the majority of whom are also persons with obesity. This contributes to diabetes as the seventh leading causes of death,[30] though some researchers posit that mortality from diabetes is higher than is currently acknowledged.[31]

A change is in how these "twin epidemics" are treated is crucial and starts with addressing the issue directly. Treatment of patients with obesity and associated type 2 diabetes is exacerbated by the fact that many patients have never been diagnosed formally.[32] Weight management discussions long have been a sensitive topic for doctors to broach with patients, made worse by a lack of time and training. Further, patients with obesity report that they are treated with less regard and respect,[33] so they may be reluctant to seek medical counsel. As a result, many do not realize that even a small, three percent sustained weight loss can reduce the risk for the development of type 2 diabetes and produce a clinically meaningful reduction in triglycerides, blood glucose, and other risk factors for cardiovascular disease.[34]

Until such time that treatment for obesity and related diseases is prioritized, it is incumbent on health care systems and the medical community to proactively change how they treat these patients and their diseases to adequately address the medical and financial challenges inherently associated with their conditions. Lifestyle change is the best option for long-term benefits and offering medically supervised VLCDs provides value-added care. VLCDs offer patients convenience and results that lead to an improved patient experience, and health care systems benefit from a one-stop-shop approach that allows them to maintain patient records, referrals, and revenues within the system.

Table 1: Current Research Supporting Meal Replacement Interventions (2016-2020)

** While research affirming the effectiveness of VLCDs has been ongoing for more than 20 years, research cited here was restricted to publication within the past five years. The recency and increased frequency of these articles demonstrate greater awareness and acceptance by the medical community of this approach to benefit both diabetic and nondiabetic patients with obesity.*

Author	Year	Method	Article	Journal	Intervention	Findings
Arguello *et al.*	2020	Retrospective review	Patients with prediabetes or type 2 diabetes mellitus in a medically supervised program	The Journal for Nurse Practitioners	VLCD	A medically supervised VLCD program can decrease the risk of developing type 2 diabetes mellitus by reducing or bringing into target HbA1c levels, resulting in improved metabolic health outcomes.
Brown *et al.*	2020	Randomized trial	Low-energy total diet replacement intervention in patients with Type 2 diabetes mellitus and obesity treated with insulin: A randomized trial	BMJ Open Diabetes Research & Care	Total diet replacement	Insulin dependent patients with obesity and type 2 diabetes following a total diet replacement achieved greater weight loss, reduced or stopped insulin therapy, and improved glycemic control and QoL.
Evert *et al.*	2019	Consensus report	Nutrition therapy for adults with diabetes or prediabetes: A consensus report	Diabetes Care	Various	The American Diabetes Association report recognizes meal replacements as part of a weight loss plan for to enhance weight loss in people with diabetes.
Lean & Leslie	2018	Randomized trial	Primary care weight management for type 2 diabetes: The cluster-randomized Diabetes Remission Clinical Trial (DiRECT)	The Lancet	Total diet replacement	After following a stepped program including total diet replacement, food reintroduction, and a supported long-term weight loss maintenance structure, nearly half in the intervention (n=149) achieved remission and went off their antidiabetic medications, suggesting diabetic remission is practical target.
Guo *et al.*	2018	Randomized controlled trial	Effects of a meal replacement on body composition and metabolic parameters among subjects with overweight or obesity	Journal of Obesity	Meal replacement	After using a dinner meal replacement for 12 weeks, participants experienced significant improvements in body weight, BMI, waist circumference, fat-free mass, body fat mass and blood glucose. The authors concluded that meal replacements were effective for weight loss and metabolic parameters, though long-term use is unsustainable due to energy restrictions.
Rehackova *et al*.	2017	Interviews	Acceptability of a very-low-calorie diet in type 2 diabetes: Patient experiences and behavior regulation	DieabeticMedicine	VLED	Participants who followed a VLED stated they were motivated by the prospect of diabetes remission, weight loss, and health improvements, which was sustained by improved physical and psychological conditions. In addition to rapid weight loss, participants experienced improved blood glucose levels, social support and increased well-being. Although it required effort, participants found adhering to the diet for 8 weeks was easier than they expected it to be.
Sellahewa & Khan	2017	Systematic review	A systematic review of evidence on the use of a very low calorie diets in people with diabetes	Current Diabetes Review	VLCD	This review of the effects of a VLCD on type 2 diabetics included 17 studies from 1986 - 2013, running from 5 days to 6 months. Findings included weight loss, Hba1c reduction, cardiovascular benefits through decreased cholesterols, and systolic and diastolic blood pressure (which continued through follow up in several studies).
Goday et al.	2016	Randomized trial	Short-term safety, tolerability and efficacy of a very low-calorie-ketogenic diet interventional weight loss program versus hypocaloric diet in patients with type2 diabetes mellitus	Nutrition & Diabetes	VLCK	Participants in the intervention followed a phased weight loss programs starting with total meal replacement, then phasing in natural proteins until 90% of weight loss goal was achieved. This group had significantly greater weight loss and reduction in waist circumference, HbA1c and glycemic control.
Parretti *et al.*	2016	Systematic review	Clinical effectiveness of a very-low-energy diets in management of weight loss: A systematic review and meta-analysis of randomized controlled trials	Obesity Review	VLED	This meta-analysis of randomized trials concluded that VLEDs, in combination with behavioral programs, were more effective that behavioral programs alone in achieving greater long-term weight loss. Their tolerability and minimal adverse affects suggest VLCDs could be more widely used.
Steven *et al.*	2016	Longitudinal single-center study	Very low-calorie diet and 6 months of weight stability I type 2 diabetes: Pathophysiological changes in responders and nonresponders	Diabetes Care	VLCD	Diabetic participants (n=30) followed a VLCD for 8 weeks without taking antidiabetic medications and all lost weight and kept it off for 6 months. After returning to an isocaloric diet,12 patients had a fasting plasma glucose <7 mmol/L, and 13 achieved it after 6 months. Blood pressure, triglycerides and non-HDL cholesterol levels improved in all participants and held at 6 months, suggesting type 2 diabetes mellitus is reversible.
van Wyk & Daniels	2016	Review/case discussing	The use of very low calorie diets in the management of Type 2 diabetes mellitus	South African Journal of Clinical Nutrition	VLCD	Participants followed a phased VLCD program going from 3 shakes daily to 2 shakes plus a lean protein meal, then one shake per day for maintenance. Results showed reduction in weight, waist circumference, BMI, fasting blood glucose, and pre-lunch and pre-dinner glucose. Improvements to glucose levels are noteworthy because the insulin-using participants had diabetes for 15 years and reduced their insulin use by 43%. Participants had greater levels of enthusiasm and motivation than with previous programs, leading to greater success.

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