White Paper

MEDICAL OBESITY TREATMENT: CLINICAL JUSTIFICATION
RESOLUTION AND/OR SIGNIFICANT REDUCTION OF CHRONIC MEDICAL CONDITIONS CAN BE ACHIEVED BY SUCCESSFULLY TREATING OVERWEIGHT AND OBESE PATIENTS

For more than 40 years, Robard Corporation's comprehensive medical and non-medical obesity treatment programs and state of the art nutrition products have enabled a vast network of physicians, large medical groups, hospital systems and clinics to maximize profit, grow their business, and successfully treat thousands of overweight and obese patients.

THE OBESITY EPIDEMIC

New estimates suggest that more than two-thirds of Americans are either overweight or obese.

	Men	Women
Overweight	39.96% (36.3 million)	29.74% (nearly 28.9 million)
Obese	35.04% (31.8 million)	36.84% (nearly 35.8 million)

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TYPE 2 DIABETES

Diabetes is a worldwide epidemic that causes significant morbidity and mortality. Obesity is a major risk factor for the development of type 2 diabetes; therefore, prevention and treatment of obesity is of utmost importance to help control or minimize the effects of type 2 diabetes. Studies show that metabolic control of diabetes can reduce the associated complications. These studies and recent guidelines recommend the importance of proper nutrition and weight loss as critical components to achieving the treatment goals, including glycemic, blood pressure and lipid control. The Very Low Calorie Diet (VLCD) is one approach that can improve all three of these goals. Recent research has elucidated the pathophysiology of diabetes, suggesting that insulin resistance and beta-cell dysfunction as key components. Weight loss can address the underlying pathophysiology of type 2 diabetes, even within one week on a VLCD. Diet-induced weight loss through a VLCD removes stores of ectopic fat outside the fat cell, improving beta-cell function, as well as blood pressure and cholesterol. This is often associated with a reduction in medications to treat type 2 diabetes and an improved quality of life. The benefits of weight loss through a VLCD for individuals with type 2 diabetes include addressing the underlying pathophysiology which may lead to long term metabolic control. Studies show not only an improvement in glucose control, but also reductions in blood pressure and cholesterol. Most patients have improved quality of life measures as well as reducing medications and SMBG.

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CARDIOVASCULAR DISEASE

Obesity significantly increases the risk of both arterial and venous diseases. The incidence of coronary heart disease (CHD), congestive heart failure (CHF), stroke, atrial fibrillation (AF), and deep venous thrombosis (DVT) increases with increasing BMI. The relationship of obesity to CHD and stroke is probably mediated through traditional risk factors such as dyslipidemias, insulin resistance (IR), and hypertension, as well as novel factors such as increased systemic inflammation and AF. Dyslipidemias, insulin resistance and CHF are further linked through the concept of "lipotoxicity," which suggests that triglyceride accumulation in the liver (nonalcoholic fatty liver disease — NAFLD), in muscle (especially cardiac myocytes) and the pancreatic beta cell lead to hepatic IR, decreased myocardial function and loss of beta cell insulin release. Recently, a study of obese adolescents showed, on cardiac MRI, significant alterations in myocardial tissue architecture (increased interstitial matrix) that resulted in diastolic dysfunction; this finding correlated with IR and high hs-CRP. Significant weight loss has been shown to reduce blood pressure, improve insulin sensitivity and lipids—all of which should have an important benefit on cardiovascular risk. The safety of a VLCD in patients with established heart disease is important, as well as in patients without known heart disease, but who have many of these risk factors. Significant weight loss from a VLCD can have a benefit on both systolic and diastolic cardiac function, especially in patients with NYHA Class II/III heart failure. This may result from improved myocardial contractility (by reduced lipotoxicity, as described above) as well as from reduced systolic and mean arterial blood pressure. Weight loss will also improve the risk for initial or recurrent lower extremity DVT, improve claudication symptoms from PAD, and reduce the risk for atrial fibrillation by improving obstructive sleep apnea.

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HYPERTENSION

Hypertension affects nearly one third of the American population with a higher prevalence among individuals with obesity. Many patients with hypertension require increasing doses of medicine as they age and/or gain weight. Lifestyle modifications that demonstrate a decrease in blood pressure include: weight loss, exercise, decreased sodium intake, smoking cessation and mindfulness/meditation practice. For individuals who have hypertension, participation in a VLCD program has been proven beneficial to better control hypertension and/or eliminates medications. As a result of weight loss from a VLCD, patients often experience about a 10 percent decreased risk of heart disease, stroke, a-fib and AAA while on a VLCD. In addition, as patients are able to decrease their hypertension medications, they enjoy fewer medication side effects and a decreased risk of medication interactions.

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CANCER

As many as 84,000 cancer diagnoses each year are attributed to obesity, and overweight and obesity are implicated in 15 percent to 20 percent of total cancer-related mortality. Obesity has been associated with greater risks of postmenopausal breast cancer and colon cancer and cancers of the prostate, kidney, pancreas, esophagus, gallbladder and others. Obesity is associated with worsened prognosis after cancer diagnosis and also negatively affects the delivery of systemic therapy, contributes to morbidity of cancer treatment, and may raise the risk of second malignancies and comorbidities. Research shows that the time after a cancer diagnosis can serve as a teachable moment to motivate individuals to adopt risk-reducing behaviors. For this reason, the oncology care team—the providers with whom a patient has the closest relationships in the critical period after a cancer diagnosis—is in a unique position to help patients lose weight and make other healthy lifestyle changes.

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ASTHMA

The incidence of asthma is 1.47 times higher in obese people than non-obese people, and a three-unit increase in body mass index is associated with a 35 percent increase in the risk of asthma. A 2015 study by the American College of Chest Physicians supports the active treatment of comorbid obesity in individuals with asthma. Weight loss in obese adults with asthma can improve asthma severity, airway hyperresponsiveness (AHR), asthma control, lung function, and quality of life. These findings support the need to actively pursue healthy weight-loss measures in this population.

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PRE/POST-SURGICAL BENEFITS

Patients that consumed a liquid diet presented a positive effect on reducing visceral fat (VF) and greater weight loss than normal diet. Very Low Calorie Diets presented benefits offering a protective effect during the preoperative stage. In a prospective, randomized, multi-center study in patients undergoing laparoscopic gastric bypass procedures (LRYGBP) had fewer postoperative complications following a two-week VLCD. Surgeons, who were blinded as to who received the diet, also rated the operations as easier in those who received the diet. Utilizing a VLCD also increases the likelihood of patients becoming bariatric surgical candidates. When bariatric surgery is inadvisable, the most common reason cited is non-alcoholic fatty liver disease (NFLAD). Bariatric surgical candidates can reduce their liver size using a VLCD, resulting in a much higher likelihood of being eligible for bariatric surgery. What's more, a standalone medically-supervised VLCD allows you to capture and successfully treat patients that are not eligible for surgery.

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DYSLIPIDEMIAS

Many obese patients will have one or more abnormalities in lipid/lipoprotein levels. The most frequent lipid disturbance associated with obesity is elevated triglycerides (TG), which is the result of accompanying insulin resistance. Not all obese patients have insulin resistance (termed "metabolically-normal obesity") and hence, won't have high TG, but this is a minority (less than 20 percent). Obese patients with the metabolic syndrome, non-alcoholic fatty liver disease (NAFLD), pre-diabetes or type 2 diabetes are all more likely to have TG levels > 150 mg/dL. If there are accompanying genetic predispositions to disturbed TG clearance as well, obesity can worsen the levels to the severe range of > 500 mg/dL. In patients with TG > 150 mg/dL, the high density lipoprotein (HDL) cholesterol will frequently be less than desirable (< 40 mg/dL in men, < 50 mg/dL in women) due to intravascular remodeling to a smaller particle. Similarly, the calculated low density lipoprotein (LDL) cholesterol may be less indicative of the true atherogenic particle number because of a smaller size. In such situations, the non-HDL cholesterol (which is the total cholesterol minus HDL-C) level will be higher than

optimal (> 130 mg/dL) despite a "normal" LDL-C. For those practitioners who use specialized lipid testing, a discordantly high apoprotein B and LDL particle number will frequently be seen when TGs are high. Obesity does not usually cause high total cholesterol; however, with an associated genetic predisposition, the total may be significantly above 200 mg/dL. There are several clinical observations that can be made about dyslipidemias when a VLCD is initiated:

1. The higher the baseline TG, the greater the percent reduction.
2. The reduction in TG begins early and persists throughout the active weight loss phase.
3. The reduction in total cholesterol and LDL-C begins early but may slowly increase (but not back to baseline if polygenic or familial hypercholesterolemia is absent) throughout the weight loss.
4. HDL-C will go down and stabilize during the weight loss, and slowly increase after resumption of a maintenance diet.
5. Lipids/lipoproteins will improve on a VLCD even if patients take statins +/- other lipid-modifying drugs. The degree of change is variable, but may be significant enough that consideration for discontinuation of some (niacin, fibrates, omega 3) or dose reduction for statins are possible.

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OSTEOARTHRITIS

Osteoarthritis (OA)—a progressive "wear and tear" disease of the joints—is frequently associated with obesity. The need for a total knee arthroplasty (TKA) is estimated to be at least 8.5 times higher among patients with a body mass index (BMI) greater than or equal to 30. In addition, the odds of sustaining musculoskeletal injuries is 15 percent higher for persons who are overweight and 48 percent higher for people who are obese, compared to persons of normal weight.

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INFERTILITY

Obesity can be a risk factor for infertility and weight loss can often improve success of conception. Although treatment of obesity may improve fertility and pregnancy outcomes, infertility may have several underlying factors; therefore, a comprehensive evaluation of the couple, male and female, is important. For females, ovulatory dysfunction may be the closest association with obesity and is more commonly related to polycystic ovarian syndrome (PCOS). Guidelines have been updated for the treatment of PCOS. These guidelines continue to recommend weight reduction. Weight reduction may also reduce obstetrical complications and improved abnormal glucose metabolism, which is common, in women with PCOS. For males, weight loss may increase testosterone levels and improve sperm quality. Weight loss with a VLCD has been instrumental in assisting many successful pregnancies. Often, a 5 percent weight loss will markedly improve ovulation, while a 10 percent weight loss further improves the chances of pregnancy.

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LIVER ENZYME ABNORMALITIES

Many patients entering into a VLCD program present with elevated transaminases. The majority of the time, this elevation is due to fatty liver. Research shows that fatty liver responds well to weight loss and biopsies demonstrate improvement in hepatic fatty liver infiltration. Since the majority of time patients who enter into a program presenting with elevated transaminases resulting from fatty liver, a VLCD is beneficial. Pre-bariatric surgery patients also benefit from a VLCD. Studies have shown a 30 percent reduction in liver volume, with 80 percent of the decrease within the first two weeks. Most recommendations are for two weeks, with optimal combinations of liver size and visceral fat loss around 12 weeks.

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MORE STATISTICS TO CONSIDER

1. Approximately 20 percent of cancer cases among women and 15 percent of cancer cases among men are attributable to obesity.
2. Both overweight and obesity at midlife independently increase the risk of dementia, Alzheimer's disease and vascular dementia.
3. In the United States, an estimated 24.2 percent of kidney disease cases among men and 33.9 percent of cases among women are related to overweight and obesity.
4. Obese individuals are at greater risk of nonalcoholic steatohepatitis (NASH), a liver disease which can lead to cirrhosis, in which the liver is permanently damaged and no longer able to work properly. NASH is one of the major causes of cirrhosis in America, behind only hepatitis C and alcoholic liver disease.
5. 68.8 percent of individuals diagnosed with arthritis are overweight or obese.
6. Children born to obese mothers are twice as likely to be obese and to develop type 2 diabetes later in life.

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