Introduction to Very Low Calorie Diets (VLCDs)

Justin D. Puckett, DO, FACOFP, FAAFP, FOMA
June 2019

Northern Michigan Osteopathic Association
Disclosures

- No applicable conflicts of interest

- I utilize VLCDs in the management of my patients including commercial products, but have no relationship outside of that of a customer

- I serve on several Pharmaceutical Speakers Bureaus, but none create a conflict

- I am a weight loss patient and lost 180 pounds utilizing a VLCD 8 years ago
What makes up a Very Low Calorie Diet (VLCD)?

- Not just a diet low in calories!
- Multidisciplinary program
  - Caloric Control
  - Medical Management (Physician Supervision)
  - Behavior Modification
  - Nutrition Education
  - Increased Physical Activity
  - Integrated with Individual or Group Support
- Focuses on lasting lifestyle changes
Phases of VLCDs

- Active
  - No greater than 12 weeks continuous
- Transition
  - Usually at least 6 weeks
- Long Term Maintenance
  - Lifetime
Food in a VLCD

- Nutritionally complete shakes, bars and/or soups (and beyond)
- Formulas designed with all needed macro and micronutrients
- Requires physician supervision & not available as stand-alone, do-it-yourself products
- Differs from the grocer, those products are partial meal replacements, 1 or 2 per day, not nutritionally complete
Why offer such programs?

- VLCDs are within many chronic care treatment guidelines
- Is only allowed to be done under physician supervision
- Physician office is a comfortable and ideal environment
- Established relationship with patient, trusted, unbiased
- Meaningful weight reduction & lasting behavior changes are a part of your treatment goals
- Effective non-surgical and pre-surgical option for weight reduction and comorbid condition improvement
Why is there not widespread utilization

- You are already busy
- Lack of experience
- Weight has often been a difficult topic to address, treat, and find long term success
- Patient expectations not reasonable
- Cost
- Lack of insurance coverage
Obesity Review

- Multifactorial chronic disease\textsuperscript{4}
- 1 in 3 adults obese\textsuperscript{5} (BMI > 30)
- 2 in 3 adults overweight or obese (BMI > 25)
- 5-10 percent weight reduction is medically significant\textsuperscript{8,9,10}
- Those with BMI > 40 continues to climb, increasing more than 600 percent since 1960\textsuperscript{5}
<table>
<thead>
<tr>
<th>Common Medical Conditions Treated with Weight Loss[^57]</th>
</tr>
</thead>
<tbody>
<tr>
<td>○ High Blood Pressure</td>
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<tr>
<td>○ High Cholesterol</td>
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<tr>
<td>○ Metabolic Syndrome</td>
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<tr>
<td>○ Type 2 Diabetes</td>
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<tr>
<td>○ Coronary Heart Disease</td>
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<tr>
<td>○ Stroke</td>
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<tr>
<td>○ Gallbladder Disease</td>
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<tr>
<td>○ Fertility or Pregnancy Issues</td>
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<tr>
<td>○ Decreased Libido and Erectile Dysfunction[^58]</td>
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<tr>
<td>○ Joint Problems and Osteoarthritis</td>
</tr>
<tr>
<td>○ Sleep Apnea and Other Breathing Problems</td>
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<tr>
<td>○ Some Cancers</td>
</tr>
<tr>
<td>○ Insulin Resistance, Pre-diabetes, PCOS</td>
</tr>
<tr>
<td>○ Mood Disorders including Depression, Anxiety, others</td>
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<tr>
<td>○ Elevated Liver Enzymes, Liver Disease</td>
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<tr>
<td>○ Incontinence</td>
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<tr>
<td>○ Decreased Physical Function, Endurance and Vigor</td>
</tr>
</tbody>
</table>
Background

- VLCDs used since 1930s
- Multiple studies demonstrate short and long term success\textsuperscript{12,13,14,15}
- Indicated for BMI > 30 or BMI > 27 with comorbidities
- Treat Obesity, improve other comorbid chronic conditions
- Included in commonly used treatment guidelines\textsuperscript{18}
  - AACE\textsuperscript{16}, OMA\textsuperscript{17}, AHA, Endocrine Society, ACC
Study results

- Long term 5 year follow up study, measuring 5% loss maintained at 5 years\(^{19}\)
  - 77.5% women
  - 59.9% men
- 20,000 people, 22 week program\(^{20,21,22,23,24,25}\)
  - Average loss of 52 pounds, >20 percent of body weight
  - 8 point BMI reduction
  - 87 percent reached 10 percent or greater loss
  - 83 percent of weight loss, fat mass
Study results

- Multiple studies demonstrate lasting clinical changes\textsuperscript{8,9,10,12}
  - Metabolic markers
  - Adipose distribution
  - Insulin resistance and sensitivity
  - Many others
Meal Replacements

- Differ in presentation, flavor, texture, not macronutrient content
- 500-800 kcal per day, (800-1200 is a LCD)
- 100% of RDI of micronutrients and minerals
- All inclusive, no other calorie containing food consumed
- Usually 5 items per day (8am,11am,2pm,5pm,8pm)
- Greater the food choices, greater the intake, stimuli narrowing\textsuperscript{29,30,31}
<table>
<thead>
<tr>
<th>Typical Meal Replacement Composition</th>
<th>Per item</th>
<th>Per day (5 items)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calories</td>
<td>160</td>
<td>800</td>
</tr>
<tr>
<td>Protein (g)</td>
<td>14</td>
<td>70</td>
</tr>
<tr>
<td>Carbohydrate (g)</td>
<td>20</td>
<td>100</td>
</tr>
<tr>
<td>Fat (g)</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>Sodium (mg)</td>
<td>220</td>
<td>1100</td>
</tr>
<tr>
<td>Potassium (mg)</td>
<td>470</td>
<td>2350</td>
</tr>
<tr>
<td>Fiber (g)</td>
<td>0-4</td>
<td>0-20</td>
</tr>
<tr>
<td>Other Vitamins and Minerals</td>
<td>20% or &gt; RDI</td>
<td>100% or &gt; RDI</td>
</tr>
</tbody>
</table>
Medical Supervision

- Intake, H and P, weight loss review, past medical, social, surgical histories, physical exam
- Review medications, adjust for weight loss
- Order and interpret, labs and diagnostic tests
- Screen for contraindications
- Assess ongoing medical comorbidities
- Set treatment plan
- Obtain consent
- Collaborate with others providers
- Oversee the program in entirety
- Insure long term plan is in place
<table>
<thead>
<tr>
<th><strong>Absolute Contraindications</strong></th>
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</thead>
<tbody>
<tr>
<td><strong>Anorexia Nervosa</strong></td>
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<tr>
<td><strong>Bulimia</strong></td>
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<tr>
<td><strong>Uncontrolled Mood Disorders or Suicidality</strong></td>
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<tr>
<td><strong>Current Substance Abuse</strong></td>
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<tr>
<td><strong>Any acute major illness such as pancreatitis, active peptic ulcer disease, acute vascular event, thrombophlebitis, acute cholecystitis</strong></td>
</tr>
<tr>
<td><strong>Type 1 Diabetes</strong></td>
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<tr>
<td><strong>Pregnancy or Lactation</strong></td>
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<tr>
<td>Relative Contraindications</td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td>Special Populations, Youth and Seniors</td>
</tr>
<tr>
<td>Binge Eating Disorder</td>
</tr>
<tr>
<td>Chronic Steroid Use (greater than 20mg of prednisone equivalents)</td>
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<tr>
<td>Recent Myocardial Infarction, Unstable Angina, Stroke, CABG, TIAs</td>
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<tr>
<td>Lactose Intolerance</td>
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<tr>
<td>Chronic Kidney Disease</td>
</tr>
</tbody>
</table>
### Relative Contraindications, cont

<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chronic Liver Disease</strong>&lt;sup&gt;37&lt;/sup&gt;</td>
<td>Initially, there may be some increase in hepatic stress as the liver restructures without the fat. Even if liver function is stable, a VLCD may worsen function for a short period of time. If tolerated, end result of VLCD is vast improvement of liver function, but caution in initiation of VLCD.</td>
</tr>
<tr>
<td><strong>Patients taking Coumadin, Lithium, diuretics</strong></td>
<td>Changes in fluid status and drug metabolism requires for close monitoring.</td>
</tr>
<tr>
<td><strong>Occupational Hazards</strong></td>
<td>Patients who may be at high risk of injury from the ordinarily mild side effects of a VLCD (notably orthostatic hypotension) must use caution.</td>
</tr>
<tr>
<td><strong>Gallstones</strong>&lt;sup&gt;37,38,39,40&lt;/sup&gt;</td>
<td>Known gallstones or dyskinetic gallbladder (incomplete emptying even if asymptomatic) may be worsened by calorie restriction initially. Consider use of Ursodiol in such patients if VLCD is selected.</td>
</tr>
<tr>
<td><strong>Hyperuricemia or history of gout</strong>&lt;sup&gt;41&lt;/sup&gt;</td>
<td>There is an increase in serum uric acid that returns to baseline by 4 weeks. Consider use of a uric acid lowering agent during active weight loss, especially for those with a past personal history of gout.</td>
</tr>
</tbody>
</table>
### Diagnostic and Laboratory Guidelines, Before, During and After VLCD

| Required pre-VLCD Diagnostic Tests | ● ECG with QTc interval  
|                                     | ● Screen for Obstructive Sleep Apnea (OSA) with Epworth Sleepiness Scale or similar  
|                                     | ● Weight Loss History and Intake Questionnaire  
| Diagnostic Tests to consider pre-VLCD (for certain populations) | ● Overnight Pulse Oximetry  
|                                                                      | ● Lab or Home Based Sleep Study (bb)  
|                                                                      | ● Chest X-ray  
|                                                                      | ● Pulmonary Function Tests  
|                                                                      | ● Ultrasound Gallbladder  
|                                                                      | ● Ultrasound Liver |
| **Required pre-VLCD Laboratory Tests** | • Complete Blood Count with differential and platelet count  
• Complete Chemistry (Metabolic) Profile including Liver Enzymes  
• Serum Uric Acid  
• Thyroid screen (TSH)  
• Lipid Profile*  
• Urine analysis |
| **Laboratory Tests to consider pre-VLCD (for certain populations)** | • Magnesium  
• Phosphorus  
• Fractionated Bilirubin  
• T4 and T3  
• Advanced Lipid Testing (NMR Lipid Profile)  
• 2 hour Glucose Tolerance Test with fasting and 2 hour insulin levels  
• GGT  
• Urine Microalbumin/Creatinine Ratio  
• Fasting or 2 hr Post Prandial Insulin  
• Sex Hormones (testosterone and estradiol) |
## Diagnostic Testing Interval

<table>
<thead>
<tr>
<th>Diagnostic</th>
<th>Examination</th>
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<tbody>
<tr>
<td><strong>EKG</strong></td>
<td>EKG should be repeated with every 50 pounds of weight loss. There is a lasting reduction of the pericardial fat which may affect voltage and conductivity pattern.</td>
</tr>
<tr>
<td><strong>Labs</strong></td>
<td>Pertinent labs will need to be followed in the normal clinical manner and post-program labs should be complete at program end, and 3 months after (to provide efficacy and adherence), or in the normal clinical fashion</td>
</tr>
</tbody>
</table>

*It should be noted that on repeat Lipid Profile, during a VLCD, the HDL number will decrease initially, but after a proper transition and maintenance of a balanced calorie diet, the HDL will return, or exceed baseline\textsuperscript{42} and will continue to improve out to at least 1 year\textsuperscript{43}.*
Physician key factors for success

- Make long term plan part of the intake commitment
- Set reasonable expectations
- Allow time, answer questions
- Utilize ancillary staff to support your role
- Insure the patient has access to someone for questions
- Prescribe exercise, slowly
- Insure all preventative measures are met
- Insure backup coverage is available in your absence
Physician timeline

- Meet with the patient, perform intake H and P, prior to any program activity
- Insure all labs and other relevant items are evaluated prior to program activity
- All patients seen weekly x 4 weeks
- Moderate to high risk seen at least every 2 weeks ongoing
- Low risk patients seen at least every 4 weeks
- Many see all patients on a weekly basis, for the entirety of the program
- Insure regular easy access for long term follow up
Common Side Effects

- Headache
- Nausea
- GERD
- Orthostatic Hypotension
- Constipation
- Diarrhea
- Transient Hair Loss
- Dry Skin
Other clinical considerations

- Vital signs recorded at all visits and per routine clinical practice
- Neck, waist and hip measurements should be done at each visit, or in routine intervals
- Encourage to weigh ONLY at weekly meetings, in physician office
Behavioral Health Component

- Individual or group
- Multi-disciplinary
- Bi-directional
- Peer to peer support
- Closed vs open groups
- Separate active and transition groups, separate topics
- Lifelong, relapse prevention, long term maintenance
Physical Activity

- Exercise is critical\textsuperscript{45}, especially long term\textsuperscript{46}
- Exercise prescriptions (PAR-Q or PAR-MEDX)
- Gentle strength training ok, no heavy lifting
- Muscle mass is maintained in a proper VLCD\textsuperscript{47}
- Advance slowly, avoid exercise injuries
Transition to Conventional Food

- Meal replacements are a tool
- Start by dropping 1 or 2 meal replacements
- Add in one small meal of 4 oz meat and 0.5-1 cup vegetable
- Slowly progress to individualized diet
- If problems progressing, take a step back, ease in
- Focus on quantity and quality
- Use measuring devices and food scales
- Avoid daily weights
- Planning ahead essential
Long Term Maintenance

- Likely involve some meal replacements
- Ongoing behavioral, nutrition, exercise and medical management critical\(^{48,49}\)
- Frequent follow ups critical, usually q 2 weeks until stable, then monthly\(^{52}\), then per routine
- Weight regain occurs, multifactorial\(^{50,51}\)
- Possible Medication use\(^{33,53}\)
Special Equipment etc.

- General clinic environment, furnishings
- Flexible tape measure
- Scale, digital, increase capacity
- Body composition analyzer
- Resting Metabolic Rate (RMR) analyzer
- Location for group meeting
Staffing

- Varies greatly, all must be on same page with VLCD!
- Physician
- Clinical Staff
- Group or Program Leader
- Marketing
- Others to consider
  - Personal Trainer
  - Diabetic Educators, Dieticians
  - Counselors
  - Past participants
Getting Paid

- Meal replacements nearly always cash and carry
- Business structures diverse
- Any medically necessary visits, labs, diagnostics, should be covered when treating a comorbid condition
- Bill for primary non-obesity medical condition
- Consider DSMT, MNT, IBT for Obesity, IBT for CVD
- Group Visits
- All standard documentation rules apply
- Utilize ABN for unpaid services
One way to do it!

- Information Session or One on One meeting
- Set up Appt with Physician
- Benefit Verification
- Intake Visit, labs ordered, completed
- Labs reviewed, pt ready to begin if consents, often a second OV prior to program initiation
- Pt picks a group meeting night
- First time attendee stays after for further ‘Welcome” materials, gets Meal Replacements starting, next day
One way to do it, cont

- Existing patients present to weekly meeting, complete order for meal replacement and turn in. Staff pull while patient in meeting, make payment

- Office Visit with Physician

- Attend Group Meeting

- Pick up product
References


References


References


