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Georgetown University Medical Center
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A New Approach Against Obesity:
Safe and Effective Natural Supplements
Leading Causes of Preventable Death

Preventable Death Rate in USA (thousands)

- Low intake of fruit & Veg: 58
- High trans fatty acids: 82
- Low omega-3 fatty acids: 84
- High dietary salt: 102
- High blood glucose: 190
- Physical inactivity: 191
- Overweight - Obesity: 216
- High blood pressure: 395
- Tobacco smoking: 467

Danaei G et al., PLOS Medicine 6, e1000058, 2009
Hypothesis

The prevalence and/or severity of many chronic disorders of aging, especially obesity-diabetes, is due in part to excess consumption of rapidly absorbed carbohydrates (high glycemic load) in the modern diets.

Major Reasons:

Excess calorie load leads to obesity
Obesity causes hormonal perturbations - IR
Direct effects of CHO on glucose-insulin system - IR
Change Per Capita Consumption (1970 – 1997)

- Corn/Wheat Flour: 42%
- Hi Fructose Corn Syrup: 1240%
- Frozen Potatoes: 218%
- Soft Drinks: 207%
- Animal Protein: 7%
- Beans: 12%
CHO Facts

- In most of world, CHO provides major share of calories
- Involved in weight control
- Involved in circulating levels of glucose - insulin
- Type of CHO important – simple (refined), complex, fibers
Heavy Sugar Ingestion with Rapid Absorption

Insulin Resistance ↔ Obesity-Calories

Aging and Its Disorder
COMMON ABNORMALITIES SEEN IN CHD AND DIABETES PRODUCED BY DIETARY SUCROSE (1960s on)

**INCREASES:**

- Fat Accumulation
- Blood Pressure
- Blood Glucose
- Blood Cholesterol
- Blood Triglycerides
- Blood Uric Acid
- Blood Insulin
- Blood Corticosteroids
- Platelet Aggregation

**DECREASES:**

- Glucose Tolerance
- Insulin Sensitivity
Obesity associated with insulin resistance and vice versa.

Disturbed glucose - insulin system leads to muscle loss/fat accumulation.

Healthy glucose - insulin metabolism supports muscle mass/fat catabolism.
Diseases Related to Excess Fat Accumulation

- Obesity is clearly associated with prevalence of:
  - Hypertension
  - Coronary artery disease
  - Diabetes mellitus
  - Left ventricular hypertrophy
  - Congestive heart failure
  - Almost all forms of cancer
  
  *New England Journal of Medicine. 2002;347:305-313*

- Other studies have found that obesity is associated with:
  - Liver disease
  - Urinary Incontinence
  - Sleep apnea
  - Depression
  - Osteoarthritis
  - Sarcopenia

  *Obesity Research. 2002;10:767-773.*
Prevent Rapid Absorption CHO Load

- Avoidance refined CHO in Diet
- Viscous Fibers
- CHO Blockers
  - White bean extract – amylase, sucrase
  - L arabinose - sucrase
The glycemic index (GI) is a measure of the effects of carbohydrates in food on blood sugar levels. It estimates how much each gram of available carbohydrate (total carbohydrate minus fiber) in a food raises a person's blood glucose level following consumption of the food, relative to consumption of glucose. Glucose has a glycemic index of 100, by definition, and other foods have lower glycemic indices.
## Glycemic Index Ranges

<table>
<thead>
<tr>
<th>Classification</th>
<th>GI Range</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low GI</td>
<td>55 or less</td>
<td>fruits, vegetables, legumes, intact grains, nuts, kidney beans, beets, chick peas</td>
</tr>
<tr>
<td>Medium GI</td>
<td>56-69</td>
<td>Whole wheat, sweet potatoes, baked potatoes, basmati rice</td>
</tr>
<tr>
<td>High GI</td>
<td>70 or above</td>
<td>white bread, white rice, corn flakes, many breakfast cereals</td>
</tr>
</tbody>
</table>
Effect of Sucrose on Blood Glucose, Insulin and Glucagon
“The findings provide evidence that low-GI diets improve glycemic control...the benefit is clinically significant and similar to that offered by newer pharmacological agents.”

“In spite of its limitations, the Glycemic Index works.” An independent review by Sievenpiper & Vuksan,

“The Glycemic index information should be incorporated into exchanges and teaching material” and “...diabetic individuals should be encouraged to...include three low GI Foods into their diet daily.”
GI BLOCKERS

• Fibers

• Chitosan

* Carb Blockers
Glucose polymers
- Starch, glycogen

Amylase
- Digest to

Disaccharides
- Maltose
  - Maltase
  - 2 glucose
- Sucrose
  - Sucrase
  - 1 glucose + 1 fructose
- Lactose
  - Lactase
  - 1 glucose + 1 galactose

Monosaccharides
## Rice Starch Challenge to Rats (2 g)

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Agent (1 g)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control</td>
</tr>
<tr>
<td>Time (h)</td>
<td></td>
</tr>
<tr>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>1.0</td>
<td>54.6±6.2</td>
</tr>
<tr>
<td>2.0</td>
<td>46.5±7.9</td>
</tr>
<tr>
<td>3.0</td>
<td>33.3±6.7</td>
</tr>
<tr>
<td>4.0</td>
<td>22.9±7.2</td>
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</table>
# Sucrose Challenge to Rats (2 g)

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Agent (1 g)</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Time (h)</td>
<td>Control</td>
<td>White Bean</td>
<td>L Arab</td>
<td></td>
</tr>
<tr>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>1.0</td>
<td>34.5±2.5</td>
<td>12.5±6.2*</td>
<td>5.8±3.7*</td>
<td></td>
</tr>
<tr>
<td>2.0</td>
<td>24.1±2.5</td>
<td>9.8±3.5*</td>
<td>-5.7±3.7*</td>
<td></td>
</tr>
<tr>
<td>3.0</td>
<td>19.5±1.9</td>
<td>11.3±2.7*</td>
<td>0.1±3.5*</td>
<td></td>
</tr>
<tr>
<td>4.0</td>
<td>20.6±6.6</td>
<td>23.2±3.6</td>
<td>-4.1±4.5*</td>
<td></td>
</tr>
</tbody>
</table>
## Sucrose Challenge to Rats – Formula at Different Doses

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Sucrose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time (h)</td>
<td>Control</td>
</tr>
<tr>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>1.0</td>
<td>37.8+4.6</td>
</tr>
<tr>
<td>2.0</td>
<td>23.3+3.2</td>
</tr>
<tr>
<td>3.0</td>
<td>19.8+2.8</td>
</tr>
<tr>
<td>4.0</td>
<td>14.5+6.6</td>
</tr>
</tbody>
</table>
Mechanisms Behind Actions of CHO Blockers

Ameliorate insulin resistance
Reduce caloric intake
Increase beneficial effects of resistant starches
Subchronic Studies on Carb Blockers

- BW down trend
- SBP down
- Insulin sensitivity up
- Circulating glucose down
- HgbA1c down trend

In Vivo Human Studies

- Eleven subjects, ages 21-57 (6 female, 5 male)
- Double-blind, placebo-controlled, cross-over studies
- Experimental: Placebo plus 1.5 grams Phase 2
- Placebo: 60 grams carbohydrate (4 slices white bread, 42 grams soybean oil margarine, 4 grams Sweet N' Low spread)
- Plasma Glucose: baseline plus every 30 minutes, postprandial, for 4 hours

University of Scranton - Joe A. Vinson, PhD November 20, 2001
Conclusions:

- The area under the plasma glucose time curve (a measure of glucose absorption and metabolism) was 66% lower with a 1.5 gram dose of Phase 2.

- No negative side effects were observed.
Celleno Italian Study

- 60 overweight patients
- Most compliant out of 82 tested
- 2000 – 2200 calorie diet
- One major meal heavy in carbohydrates.
- Tablet 445 mg of Phase 2 white bean extract

<table>
<thead>
<tr>
<th>Measured Parameter</th>
<th>Test (n=30)</th>
<th>Control (n=29)</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body Weight (kg)</td>
<td>-2.93±1.16</td>
<td>-0.35±0.38</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Fat Mass (kg)</td>
<td>-2.40±0.67</td>
<td>-0.16±0.33</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Lean Body Mass (kg)</td>
<td>-0.53±0.45</td>
<td>-0.19±0.17</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Waist Circumference (cm)</td>
<td>-2.93±2.13</td>
<td>-0.47±0.39</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hip Circumference (cm)</td>
<td>-1.48±0.66</td>
<td>-0.10±0.47</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Thigh (right)</td>
<td>-0.95±0.80</td>
<td>-0.26±0.46</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Circumference (cm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adipose tissue thickness</td>
<td>-4.2±6.51</td>
<td>-0.66±2.81</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>(via skin echogram) (mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
L Arabinose Clinical Study

Procedures

• 50 non diabetic subjects (20M, 30F)
• Fasted for 12h prior to baseline blood glucose
• Consumed 70g sucrose
• Glucose @ 30, 45, 60, 90 min; Insulin @ 30, 60 min
• Same procedure but 2g of L Arabinose containing Cr with sucrose
Before and After Consumption of L-Arabinose

A Diagrammatic Representation of the Potential Changes in Fasting Blood Glucose After Consumption of a 40 grams of Sucrose
With and Without Taking an L-Arabinose/Chromium Supplement 30 Minutes Prior to Sucrose Consumption
## Effects of LA-Cr on changes from baseline of glucose and insulin with a 70 g sucrose challenge

<table>
<thead>
<tr>
<th>Parameter</th>
<th>30</th>
<th>45</th>
<th>60</th>
<th>90</th>
<th>AUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose n=50</td>
<td>-19.1%**</td>
<td>-26.1%***</td>
<td>-24.8%**</td>
<td>-27.1%*</td>
<td>-18.4%***</td>
</tr>
<tr>
<td>Insulin</td>
<td>+11.9%</td>
<td></td>
<td>-28.2%***</td>
<td>-28.2%**</td>
<td></td>
</tr>
</tbody>
</table>
Insulin Sensitizers (Thiazolidinedione)

- Chromium
- Cinnamon
- Maitake Mushroom (Fraction SX)
- HCA (*Garcinia cambogia*)
- Bitter Melon
Natural Substance Enhancing Insulin Sensitivity

**Trace Elements:** Cr, Mg, Zn, Vd

**Various Antioxidants:** a Lipoic Acid, CoQ10, Vitamin C

**Botanicals:** Maitake Mushroom, Cinnamon, Bitter Mellon, *Garcinia cambogia* (HCA)
The Multi-Mechanistic Fat Loss Plan

**APPETITE CONTROL** - *Super CitriMax®*: We added extra strength doses of this patented product that is proven to suppress appetite as well as reduce conversion of carbohydrates to fat. In a Georgetown University 8-week study, the Super CitriMax group lost an average of 12 pounds each compared to 3 pounds for the placebo group.

**CALORIE BURNER** - *Green Tea Extract*: Proven to burn up to 5% more calories per day – which equals one meal per week! It also helps keep off the weight! In a recent study, a group that had lost 13 lbs was divided in two groups. One received green tea extract, the other a placebo. The green tea group continued to lose weight while the placebo group actually regained 40% of the weight they had lost!

**INSULIN SENSITIZER - FAT BURNER** - *Chromium*: A patented form of chromium, this ingredient does more than just burn fat. When you start to lose weight it makes sure weight loss comes from fat, not muscle. In one study, in which two groups lost the same weight, the chromium group lost 84% fat and 16% muscle. The placebo group lost 92% muscle and 8% fat!

**CARBOHYDRATE BLOCKER** - *Phase 2*: A revolutionary FDA reviewed product that has been proven to neutralize the starch found in foods like potatoes, breads, pasta, rice and corn. In a recent UCLA study, the group that received the Phase 2 lost twice as much weight as the placebo group.

**LEAN ENHANCEMENT** - *Conjugated Linoleic Acid (CLA)* is made from 100% Tonalin brand CLA, the purest, most absorbable and most researched variety. Decades of research indicate that CLA actually changes body composition by reducing body fat and increasing or preserving lean muscle mass. Derived from natural safflower oil, CLA inhibits lipoprotein lipase, an enzyme that breaks down fat from our diets. Once the fat is broken down, it is stored in the body. By suppressing this enzyme, CLA helps reduce the amount of fat that is broken down and, therefore, the amount of fat that is stored.
Methods and Procedures

- 20 subjects (males and females). Given advice on diet and exercise.

- Open labeled study over two months

- Group received recommended doses of each ingredient in formula.

- Fat and non fat body masses were estimated using DEXA
Positive Changes (lbs) in Body Composition During a 60-day Clinical Trial

- Weight Loss: -0.9 lbs, P = 0.17
- Fat Loss: -4.3 lbs, P = 0.0003
- Lean Gain: +3.3 lbs, P = 0.006
- Lbs of Body Composition Improvement: +7.6 lbs
Diabetes Prevention Clinical Trials
Drug Carb Blockers


Diabetes Clinical Prevention Trials

Drug Insulin Sensitizers


Safe Supplements that Protect Against Sugar-Induced Maladies

- 1. Insulin Sensitizers
- 2. ACE Inhibitors
- 3. Antioxidants
- 4. Anti hypertensive
- 5. Anti inflammatory