A Pilot Clinical Study of a Nutraceutical Formulation in Overweight Subjects

Dylan Ren
University of Wyoming
Laramie, WY
Type-2 Diabetes

- Type 2 diabetes mellitus (T2DM) is growing at epidemic proportions
  - ~350 million people worldwide
  - ~30 million in the U.S.

- Diabetes is an independent risk factor for cardiovascular disease (CVD)
  - Leading cause of morbidity and mortality in the United States
Type-2 Diabetes and the Obesity Connection

- In the US about $\frac{2}{3}$ of the adult population is either overweight or obese.
- Growing epidemic of obesity is one of the reasons for increased prevalence of diabetes.
- Number of children and adolescents with obesity and diabetes is on the rise.
Age-Adjusted Prevalence of Obesity and Diagnosed Diabetes Among U.S. Adults Aged 18 Years or older

**Obesity (BMI ≥30 kg/m²)**

- **1994**
- **2000**
- **2010**

**Diabetes**

- **1994**
- **2000**
- **2010**

Insulin Resistance

- Impaired cellular response to insulin
- Prediabetic stage
- Precedes the development of full-blown type 2 diabetes
- Often is seen during transition from obesity to type-2 diabetes
Diet?
Insulin Resistance

- **Management:**
  - Diet (Therapeutic Life Style Modification)
  - Exercise
  - Pharmacotherapy
  - Nutritional supplements
GlyacaCare™ Plus

- Formulation containing:
  - Cinnamon extract
  - Piperine
  - *Pterocarpus marsuipum* extract
  - Zinc monomethionine
  - Copper lysinate
  - Chromium polynicotinate
  - Bismaltoxo-vanadium
Objective

- To determine the efficacy of the formulation to
  - Improve insulin sensitivity and glucose tolerance in overweight adults
  - Reduce oxidative stress and inflammatory markers
Design

- Randomized, double-blind, placebo-controlled study
- 12-week intervention
- Inclusion criteria:
  - Body mass index (BMI) between 25-40 kg/m²
  - Not diabetic, not pregnant, does not have any other chronic disease
Enrolled (n=23)

Excluded (n=3)
- Did not meet inclusion criteria (n=2)
- Declined to participate (n=1)

Randomized (n=20)

Placebo (n=10)
GlycaCare Plus (n=10)

Subjects who completed the study (n=17)
  Withdrew due to pregnancy (n=1)
  Withdrew because of relocation (n=1)
  Withdrew citing difficulty in swallowing capsules (n=1)
Inflammatory Markers

**C-Reactive Protein**
- Placebo: -15, -10, -5, 0, 5, 10
- Glycacare: -15, -10, -5, 0, 5, 10

**Interleukin-6**
- Placebo: -20, -10, 0, 10
- Glycacare: -20, -10, 0, 10
Molecular Oxygen - A Biradical
Reactive Oxygen Species

- Oxygen
- Superoxide Anion
- Singlet Oxygen
- Hydrogen Peroxide
- Fenton Reaction
- OH Radicals
- Water
Oxidant Damage

- **Lipids:**
  - Peroxidation

- **Proteins:**
  - Denaturation and crosslinking

- **DNA:**
  - Strand-breaks, base degradation

- **Genes activation:**
  - c-fos, c-jun, NF-KB
Isoprostane-ELISA
Marker of Oxidative Stress

8-Isoprostane

Change from Baseline (pg/mL)

Placebo

Glycacare

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Conclusion

- Short-term intervention with GlyacaCare….
  - Did not affect body weight, serum insulin, serum glucose or hemoglobin A1C
  - Showed a tendency to decrease HOMA-IR index, improve glucose disposal
  - Reduced oxidative stress
- Further studies with a larger n, focussed on insulin-resistant subjects would help ascertain the utility of this formulation
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