

Efficacy of Novel Biologically Active Food Supplement in Type 2 Diabetes Mellitus: A Double-Blind Prospective Clinical Trial

Abstract No:

2606-PO

Abstract Type:

Poster

Author(s):

VINOD K. PODICHETTY, MISHEL WESHLER

Location(s):

Miami, FL, Nazareth Illit, Israel

Abstract Body:

Despite significant achievements in management of diabetes, its prevalence has risen exponentially creating paramount need for alternative therapies. Balanced modulation of several targets provides superior therapeutic outcome.

The purpose of the study is to investigate the safety and efficacy of a novel biologically active food supplement (Sugar Crush) in decreasing blood glucose level (BGL) in type 2 diabetes mellitus (T2DM).

Between *June 2008-July 2009*, 154 patients were screened for T2DM and inadequate glycemic control. 51 subjects meeting inclusion/exclusion criteria were enrolled in a prospective clinical study. All patients ($n=51$) were studied 6 months with first 3 weeks of placebo phase, followed by 14 weeks of active supplement use and observation for 3 weeks. Patients returned to active supplement use for additional 3 weeks. All participants were tested for fasting BGL once every week during 22-week period. The glucose-lowering effect was measured by comparing BGL tested at baseline, during placebo phase (Weeks 1-3), treatment with supplement (Weeks 4-17) and during no treatment period (Weeks 18-20). No other glucose-lowering medication was allowed except study medication during the course of the study.

Average age of the sample=52.6 years (23M: 28F); average reference blood glucose level (day 1) =265.7mg/dL. During the first 3-week placebo period, patients showed no detectable change in the BGL. At Week 10 (after 7 weeks of supplement use) the BGL was reduced by 47% compared to baseline; (mean±SD, day1 vs. week10, 265.7+86.2 vs. 131.6+31.7; paired t-test = -11.8, $p<0.001$) and at Week 17, BGL decreased by 59% ($p<0.001$). Between Week 18-20, during which no participant received placebo nor supplement, BGL did not decrease. Glucose lowering effect of the supplement was stable and prolonged to maintain BGL at a constant level. Patients reported satisfaction on Likert scale and no side effects during the course of the study.

The current study indicates that the new biologically active food supplement was effective in decreasing BDL in T2DM patients with no side effects and has a therapeutic promise in regulating blood glucose levels.

Category

- Nutrition - Clinical