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Research article

Pre-Diabetes Reduction from ALCAT Food Allergen Testing: A Controlled, Pilot Study

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Abstract

Introduction: Type 2 Diabetes (T2D) effects over 500 million people, worldwide, and the cost of this disease is estimated to exceeded $997 billion US dollars. T2D is comorbid with obesity and hypertension, and the purpose of this 6-month case/control study was to determine if food allergy elimination is effective in reducing the HbA1c and BMI values in Pre-diabetic (PDM) patents in the USA and Caribbean. Methods: Twenty-four PDM subjects (with obesity and hypertension) enrolled in this case/control pilot study. All subjects received nutritional counseling and aerobic exercise instructions which is the initial standard of care for PDM. Control (CON) subjects received no further treatment. Experimental (EXP) subjects also had ALCAT leukocyte reaction testing to identify sub-acute food allergens (N=250 foods). Food Allergens were eliminated for the 6-month study duration. The dependent variables in this study were changes in HbA1c and BMI values. The independent variables included changes in fat mass, blood pressure, and waist circumference. Differences were calculated using a repeated measures ANOVA. Results: After 180 days, the data revealed that EXP subjects showed reductions in A1c and BMI (-0.7 HbA1c, -1.1 BMI), while CON showed increased values (+0.5 HbA1c, +0.5 BMI), ($P < 0.0001$). EXP also showed significant changes in Blood pressure (-25% systolic, -20% diastolic), Fat Mass (-18 pounds), and waist circumference (-2”). There were not significant changes in these variables for CON subjects.

Keywords: Leukocyte reaction testing, Aerobic-surge exercises, Obesity reduction

Introduction

Globally, 537 million adults are living with diabetes, and that incidence is expected to increase by 20% to 643 million in 2030. Additionally, an estimated 350 million children and adolescents are now overweight with undiagnosed PDM [1-5] PDM plus Type 2 Diabetes (T2D) effects over 50 million people in the USA. In the Caribbean and Central America countries, T2D incidence has grown 30% in the past ten years [4-14] and is expected to reach 50% by 2045.

In the Caribbean, diabetes is 4th leading cause of death reaching almost 14% of all mortalities, and Hypertension (HTN) with heart disease are often comorbid with T2D and PDM [4-6]. Eighty percent of the world’s diabetes population reside in low to moderate income countries [46,12-15]. The current global cost of treating diabetes exceeds $997 billion US dollars which has shown a 316% increase over the last 15 years [1-10].

Weight loss has been shown to reduce and slow the evolution of PDM to T2D, however research has not shown the effect of eliminating sub-acute food allergies, which may be a contributing cause of PDM, as it has been shown in obesity [7-11]. Numerous studies have examined treating the symptoms of T2D and obesity with diet, nutrition [5-15] and therapeutic exercise

[7-11,20], however only the newest studies have examined food allergen elimination for obesity and pre-diabetes reduction [7-11].

There is a lack of clinical research examining the underlying causes of PDM and the obesity epidemic, but sub-acute food allergy elimination has long been named as a contributing factor of many diseases from migraine headaches to irritable bowel syndrome [7-11,15,16,23-29].

A recent 12-month study examined treating obesity with food allergen elimination and with using the brief, repeated Aerobic-surge exercise routine [11]. That multi-centre, case/control study (N=94, ages 18-76) compared four subject categories: 1. Food Allergen elimination with brief Aerobic-surge exercises, (5/day); 2. Food Allergen elimination alone; 3. Aerobic-surge exercises alone (5/day); and 4. Control.

All subjects received nutritional assessment, counseling, and guidance to avoid problematic foods with ingredients such as TBHQ, high fructose corn syrup, etc. The first two groups of subjects had ALCAT Leukocyte Reaction testing for food allergies which examined reactions from 237 foods (Cell Science Systems Testing, Deerfield Beach, Florida, USA). Foods that showed a significant reaction to this test were eliminated from their diet (mean 36 foods per subject) [7-11,20, 22].

The results of that study by Willis et al. were both significant and meaningful. All therapeutic groups displayed significant changes in weight, BMI, and girth measurements, however the greatest change was for Group I which employed food allergen elimination and Aerobic-surge exercises ($p < 0.0001$). That group displayed the greatest mean changes in Weight -32.2lbs (14.6kg), BMI -4.6, and Waist circumference -4.3" (10.9cm) [11].

The correlations between PDM, T2D, and obesity are substantial [1-32]. Recently the US CDC reported that the prevalence of allergies, obesity and pre-diabetes were significant, because 73% of Americans have allergies and over 80% of Americans with PDM or T2M patients are also obese, (This data came from a recent survey of 28,429 patients) [31]. The purpose of this 6-month study was to determine if food allergy elimination is effective in reducing the HbA1c and BMI values in PDM patents.

Methods

Diagnosis of PDM was accomplished with Hemoglobin A1c testing at private medical clinics with values of 5.7-6.4. The A1c test values above 6.5% yielded diagnosis of T2D and these candidates were not included in this study. Diagnosis of obesity is defined with the Body Mass Index (BMI) scale and readings > 30 are obese.

The BMI formula is;

BMI= Body Weight (kg) ÷ Height (m2)

Twenty-four (N=24) subjects enrolled in this case/control trial who were newly diagnosed with PDM plus Obesity, and these subjects were recruited from four private, primary care clinics (Peoria AZ, Clear Lake TX, and Galveston TX, and Basseterre St Kitts in the Caribbean). The mean subject age was 45, (range 18-82 years), with 2 males, and subjects of Caucasian, Hispanic, and African ethnicities. After a briefing on the procedures, risk, and benefits, each subject signed the informed consent as required by the Galveston Clinical Research IRB (#01.2021).

Then all subjects had nutritional assessment completed with 7-day diet tracking. This was used for nutritional assessment and dietary recommendation such as eliminating foods with High Fructose Corn Syrup, TBHQ, and other detrimental preservatives [11,17-19]. Plus, subjects were taught how to eat smaller, more frequent "feedings" [11,17]. For example, if one's total daily volume of food is one liter, it would be divided into five "feedings" compared to the traditional three meals per day of the same total daily volume.

All subjects were also taught how to perform the Aerobic-surge exercise protocols which started with calculation of each subject's age-specific, estimated Aerobic Threshold (AT). The Aerobic-surge protocol was shown previously beneficial [11,20], and the AT formula is:

(220 – age) x 75% = AT [7-11,20].

Subjects were instructed to perform five of the 2-minute Aerobic-surges each day and compliance was measured with daily electronic reports from all subjects. Example exercises were shown in the book "Food is the Cure for the Overweight Disease" [15] and this book was given to all subjects.

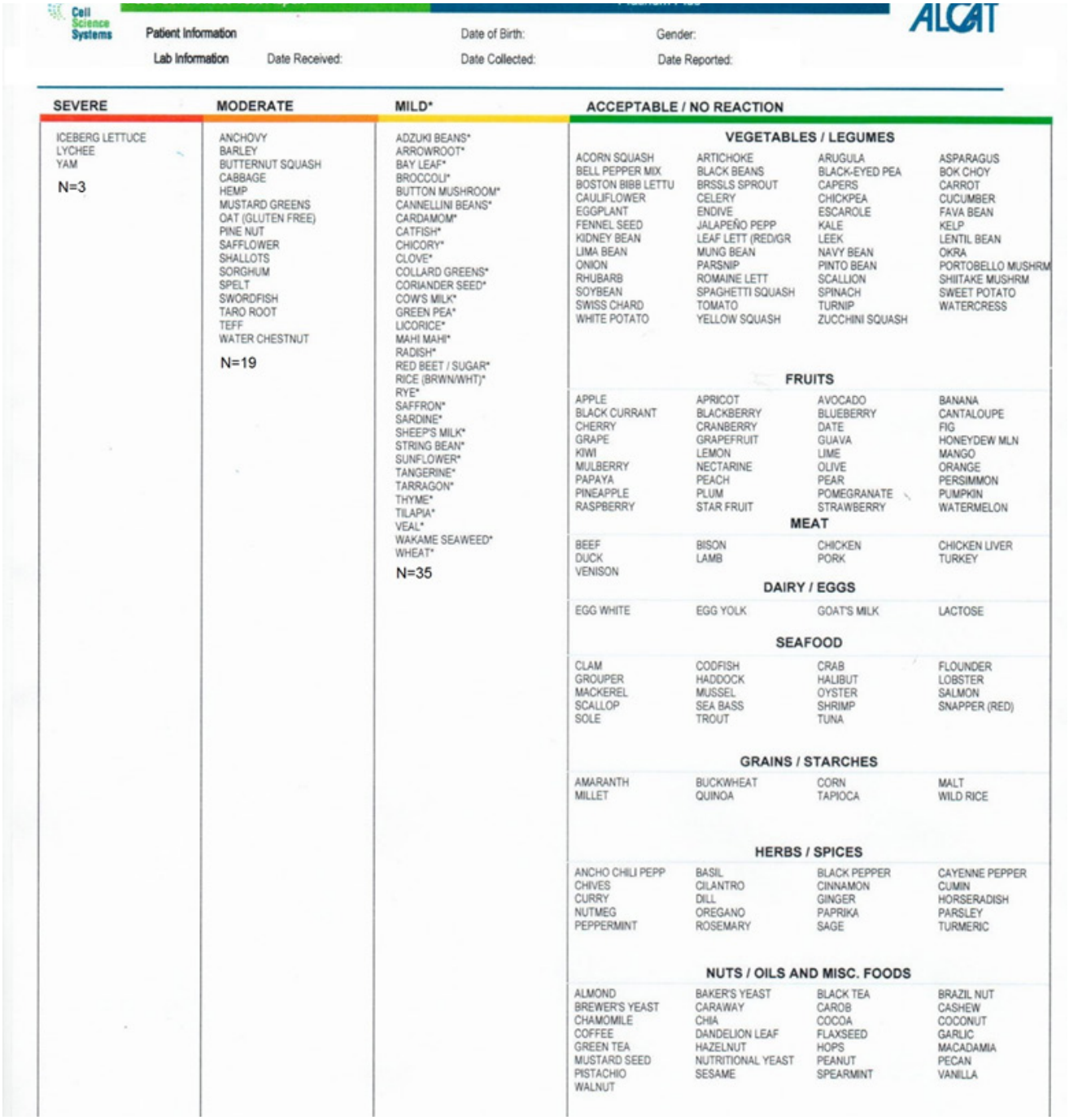
All subjects reported their compliance with weekly food diaries and their "daily count" of the total number Aerobic-surges performed of feedings were sent to the Dr. Willis daily, (such as "5/5" or "3/3").

After the nutritional assessment and Aerobic-surge exercise training, subjects chose whether they would like to be treated with diet and exercise alone, as control subjects (CON) which is the initial, standard of care for PDM, or if they would also like to be also treated with sub-acute food allergy testing and elimination using the ALCAT Leukocyte Reaction test. The Experimental (EXP) subjects (N=12) who chose the leukocyte reaction testing had three vials of blood drawn once for analysis by the Cell Science System labs (ALCAT, Cell Science Systems Labs, Deerfield Beach, FL, USA).

Results of the ALCAT test were discussed between the PI and subjects (Figure 1) and subjects were told to eliminate the allergens for the duration of this study and they were given dietary suggestions taken from the foods which showed "No significant reaction." For example, if a person showed a significant allergic reaction to a water chestnut, the PI would suggest a substitute like almonds or cashew nuts. All food allergens were eliminated for the full 6-month duration of this study.

Results

Differences were calculated using a repeated measures ANOVA. Testing after 180 days, showed a significant change in HbA1c and BMI for the EXP subjects (-0.7 A1c and -1.1 BMI) and in comparison, the CON subjects' HbA1c actually rose by (+0.5 A1c and +0.5 BMI), (Figure 2). There was a significant difference in the dependent variables of HbA1c and BMI ($P< 0.0001$, SD=0.343, F-ratio 85.6.) and there were also significant changes for EXP subjects in Blood Pressure, (-3.8 kg Fat Mass, -25% systolic BP, and -20% diastolic BP). Four subjects disenrolled: one due to pregnancy, one due to anew cardiac diagnosis, and two due to loss of interest, (2 CON and 2 EXP lost).



Cell Science Systems

Patient Information Date of Birth: Gender:

Lab Information Date Received: Date Collected: Date Reported:

ALCAT

SEVERE	MODERATE	MILD*	ACCEPTABLE / NO REACTION
ICEBERG LETTUCE LYCHEE YAM N=3	ANCHOVY BARLEY BUTTERNUT SQUASH CABBAGE HEMP MUSTARD GREENS OAT (GLUTEN FREE) PINE NUT SAFFLOWER SHALLOTS SORGHUM SPELT SWORDFISH TARO ROOT TEFF WATER CHESTNUT N=19	ADZUKI BEANS* ARROWROOT* BAY LEAF* BROCCOLI* BUTTON MUSHROOM* CANNELLINI BEANS* CARDAMOM* CATFISH* CHICORY* CLOVE* COLLARD GREENS* CORIANDER SEED* COW'S MILK* GREEN PEA* LICORICE* MAHI MAHI* RADISH* RED BEET / SUGAR* RICE (BRWN/WHT)* RYE* SAFFRON* SARDINE* SHEEP'S MILK* STRING BEAN* SUNFLOWER* TANGERINE* TARRAGON* THYME* TILAPIA* VEAL* WAKAME SEAWEED* WHEAT* N=35	**VEGETABLES / LEGUMES** ACORN SQUASH, ARTICHOKE, ARUGULA, ASPARAGUS BELL PEPPER MIX, BLACK BEANS, BLACK-EYED PEA, BOK CHOY BOSTON BIBB LETTU, BRSSLS SPROUT, CAPERS, CARROT CAULIFLOWER, CELERY, CHICKPEA, CUCUMBER EGGPLANT, ENDIVE, ESCAROLE, FAVA BEAN FENNEL SEED, JALAPEÑO PEPP, KALE, KELP KIDNEY BEAN, LEAF LETT (RED/GR, LEEK, LENTIL BEAN LIMA BEAN, MUNG BEAN, NAVY BEAN, OKRA ONION, PARSNIP, PINTO BEAN, PORTOBELLO MUSHRM RHUBARB, ROMAINE LETT, SCALLION, SHIITAKE MUSHRM SOYBEAN, SPAGHETTI SQUASH, SPINACH, SWEET POTATO SWISS CHARD, TOMATO, TURNIP, WATERCRESS WHITE POTATO, YELLOW SQUASH, ZUCCHINI SQUASH **FRUITS** APPLE, APRICOT, AVOCADO, BANANA BLACK CURRANT, BLACKBERRY, BLUEBERRY, CANTALOUPE CHERRY, CRANBERRY, DATE, FIG GRAPE, GRAPEFRUIT, GUAVA, HONEYDEW MLN KIWI, LEMON, LIME, MANGO MULBERRY, NECTARINE, OLIVE, ORANGE PAPAYA, PEACH, PEAR, PERSIMMON PINEAPPLE, PLUM, POMEGRANATE, PUMPKIN RASPBERRY, STAR FRUIT, STRAWBERRY, WATERMELON **MEAT** BEEF, BISON, CHICKEN, CHICKEN LIVER DUCK, LAMB, PORK, TURKEY VENISON **DAIRY / EGGS** EGG WHITE, EGG YOLK, GOAT'S MILK, LACTOSE **SEAFOOD** CLAM, CODFISH, CRAB, FLOUNDER GROUPER, HADDOCK, HALIBUT, LOBSTER MACKEREL, MUSSEL, OYSTER, SALMON SCALLOP, SEA BASS, SHRIMP, SNAPPER (RED) SOLE, TROUT, TUNA **GRAINS / STARCHES** AMARANTH, BUCKWHEAT, CORN, MALT MILLET, QUINOA, TAPIOCA, WILD RICE **HERBS / SPICES** ANCHO CHILI PEPP, BASIL, BLACK PEPPER, CAYENNE PEPPER CHIVES, CILANTRO, CINNAMON, CUMIN CURRY, DILL, GINGER, HORSERADISH NUTMEG, OREGANO, PAPRIKA, PARSLEY PEPPERMINT, ROSEMARY, SAGE, TURMERIC **NUTS / OILS AND MISC. FOODS** ALMOND, BAKER'S YEAST, BLACK TEA, BRAZIL NUT BREWER'S YEAST, CARAWAY, CAROB, CASHEW CHAMOMILE, CHIA, COCOA, COCONUT COFFEE, DANDELION LEAF, FLAXSEED, GARLIC GREEN TEA, HAZELNUT, HOPS, MACADAMIA MUSTARD SEED, NUTRITIONAL YEAST, PEANUT, PECAN PISTACHIO, SESAME, SPEARMINT, VANILLA WALNUT

Figure 1. Sample ALCAT test report

Discussion

These findings concurred with previous studies of food allergen elimination for obesity reduction by Lewis et al. They tested 120 overweight subjects for IgG food allergens and foods that had a positive reaction were removed for experimental subjects' diets for 90 days. These subjects saw significant changes in weight and waist/hip circumferences: Weight – 5kg and Waist circumference -5.4cm, ($P < 0.01$) [23]. One limitation of that study by Lewis et al. was that they only tested for IgG reactions.

Whereas the ALCAT Leukocyte reaction testing examines changes in the size and number of the total population of circulating white blood cells in whole blood, following individual, ex vivo challenges with standardized food extracts, thus providing significantly more information about how the total immune system responds to the particular test substance in a non-mechanism dependent manner.

While food allergy testing and elimination have been studied previously for reduction of migraine headaches and intestinal disorders [25-29], the research has not been extensive in determining the efficacy of food allergy elimination in management of Obesity or PDM reduction. However, the food allergen elimination studies have shown ideal safety with zero adverse events [7-11,27,28].

Food is touted as both the cause and the cure for PDM and obesity. Processed foods and chemicals such as aspartame have been shown to be contributing causes, while natural foods have been shown to help treat these diseases [6-15]. It has also been concluded that an elevated BMI is both a global health risk and biomarker for specific cardiovascular diseases. While Obesity is a continually growing epidemic, the cases of Obesity and

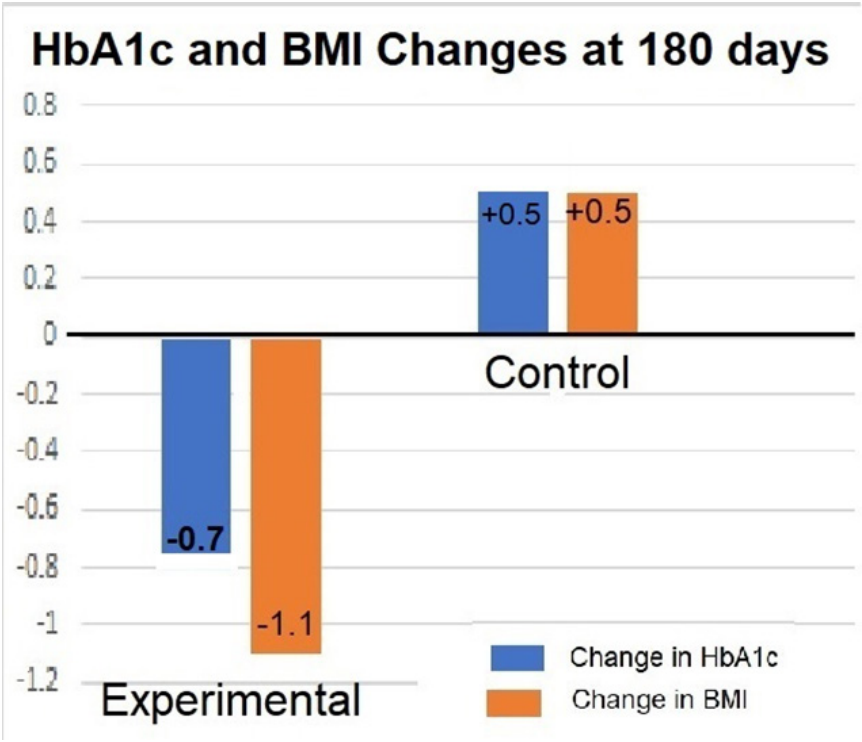


Figure 2. Results

Pre-Diabetes grew at an even greater rate during the COVID-19 pandemic [30].

Conclusion

T2D and obesity have a rapidly growing incidence in the Caribbean and publications have shown that it could be the highest region for this comorbidity [2,4,32]. The purpose of this 6-month, controlled pilot study was to determine if food allergy elimination is effective in reducing the HbA1c values in Pre-diabetic (PDM) patents.

The results of this controlled pilot study showed significant changes and differences in HbA1c and BMI as well as the independent variables ($p < 0.0001$). Next a randomized, controlled trial should be conducted to show efficacy of using food allergen elimination and the Aerobic-surge exercise protocol so the growth in PDM and obesity can be reversed.

Conflict of Interest

No conflict of interest exists between the authors and the sponsoring Cell Science Systems company. Cell Science Systems donated the ALCAT testing as well as publications fees and travel for research presentations.

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