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Full Length Research Paper

A variation on the 'Paleo' diet and its potential role in type 2 diabetes control

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In the United States alone, over 29 million individuals have diabetes. Approximately 10% of these individuals have the juvenile (or type 1) form of diabetes, with the remainder being affected by type 2 diabetes. Type 2 diabetes is marked by the lack of response to insulin, resulting in diminished glucose uptake by tissues leading to elevated blood glucose. The resulting chronic elevation in blood glucose levels cause numerous diabetes-related complications, including heart attack, stroke, kidney disease and the loss of lower limbs. The available treatment options involve lifestyle changes along with lifelong medication and blood glucose monitoring. With an economic impact of more than $250 billion annually in the US, there is an urgent need for safe and more effective long-term solutions for type 2 diabetes. Dietary modifications are a rapidly-emerging option that may address this need. Therefore, this study examined the effect of a 'Paleo' diet on type 2 diabetes. Using A1C levels to determine average glucose levels, type 2 patients were placed on a variation of a 'paleo' diet developed by the authors, which is consisted of meat and vegetables, supplemented with nuts, low glycemic fruits, and Apex Supplements. Type 2 diabetic individuals experienced a 0.9% decrease in A1C levels, with 14 out of 17 participant's A1C levels dropping below the threshold to be considered diabetic. These results highlight the effectiveness of a paleo diet combined with nutritional supplements in reversing type 2 diabetes, and offer a safe and effective treatment option for type 2 diabetes.

Key words: Type 2 diabetes, diabetes, paleo diet, dietary modifications, blood glucose, A1C, A1C levels, diabetic control, diabetes reversal, ADA diet, naturopathic, naturopathic supplements.

INTRODUCTION

Diabetes mellitus, or simply diabetes, is a disease affecting an individual's ability to properly respond to and regulate high blood glucose levels. Nearly two million new cases of diabetes are diagnosed each year in the United States, affecting 9.3% of the population (Center for Disease Control and Prevention, 2014). With an increasing incidence of risk factors such as obesity, and the rising cost of treatment and complications, diabetes is a major modern medical and economical concern. Blood glucose levels are typically assessed through the measurement of A1C (or 'glycated') hemoglobin concentrations in the blood, which are then expressed as percentages of total blood glucose, known as 'levels'. An A1C level of 6.5 or more classifies a patient as diabetic, whereas a level of 5.7 or less is considered normal.

Diabetes is separated into two types: type 1 and type 2. Type 1 diabetes has an autoimmune aspect in which a patient's insulin-producing cells, pancreatic beta cells, are destroyed. This form of diabetes, also referred to as juvenile diabetes due to the early age of onset, has no effective preventions. However, emerging therapies such as teplizumab show promise for newly-diagnosed patients (Herold, 2012). Long-term treatment is limited to careful monitoring of diet along with insulin injections to regulate blood glucose levels. In type 2 diabetes, which comprises 90% of all diabetes cases worldwide (Zimmet,

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2001), the disease is due to a decreasing sensitivity to insulin and, over the long term, an eventual decline in insulin production. Type 2 diabetes is considered preventable with proper diet and exercise, but increasing rates of obesity and decreases in physical activity contribute to an increasing incidence.

Diabetes has long been considered an irreversible disease, with research focused on prevention for type 2 diabetes and long-term therapies for all diabetic patients. For patients who have already been diagnosed with diabetes, treatments are focused on a strict dietary regimen complemented by medication. However, these treatments are by no means a diabetes cure and instead are focused on management of symptoms. In order to lower blood glucose levels, type 2 diabetic patients are also initially given metformin to reduce the release of glucose from the liver via decreased gluconeogenesis. Despite reports of potential complications regarding metformin, it is generally considered to be a safe treatment for recently diagnosed type 2 diabetes (Inzunucchi, 2014). Over time, this treatment is replaced by a combination of metformin with other medications, including insulin. However, many patients find that their diabetes progresses even with such treatment, leading to a decreased quality of life and reduced lifespan.

Previous studies have indicated that other dietary modifications, including severe caloric restrictions (600kcal/day) could reduce diabetic symptoms (Lim, 2011), while retrospective studies have identified a potential benefit of nutritional supplements on type 2 diabetes (Bradley, 2006). Recently, a large study was performed using patient-reported results, demonstrating a benefit of naturopathic treatment (Bradley, 2012). Additionally, a recent study showed that a two-week paleo diet (one in which the consumption of modern processed grains, sugars and dairy products is avoided) offered improvements in glucose control when compared to the American Diabetes Association (ADA) recommendations of whole grains, legumes, low-fat dairy, and moderate salt consumption (Masharani, 2015). Therefore, a modified diet with nutritional supplements was used as a combined method of diabetes treatment in this study, while indicators of diabetes were used to assess the treatment's effectiveness. Through a paleo diet including meat, vegetables, nuts and low glycemic fruit, complemented by a supplement regimen (administered to address any deficiencies found as a result of blood-test analysis per subject), individuals' average blood glucose levels were reduced below the threshold to be considered diabetic. In contrast to regulating blood glucose in type 2 diabetes with lifelong medication in the face of rising complications, these results highlight a treatment option able to reverse diabetic indicators.

MATERIALS

Seventeen individuals with type 2 diabetes (11 females and six males, average age 69.7 ± 1.8 years) consumed a paleo diet consisting of meat and vegetables, three times per day for three to five months. Participants were allowed to supplement their diet with whole low glycemic fruit and nuts or seeds (as listed in Appendix II) between meals. Blood samples taken from participants at this stage were analyzed and evaluated based on the guidelines developed by Kharrazian (Kharrazin, 2014) to identify any deficiencies outside of normal ranges. Apex supplements (see Appendix I) were added to the therapeutic regimen of any patients whose laboratory results fell outside of the acceptable functional range.

METHODS

Average blood glucose and three-month A1C levels were determined at the start of the study and again at the completion of the study. All diabetic participants received diabetic medications while blood sugar A1C levels were above 6.5%. A set of ten non-diabetic individuals (seven females and three males, average age 53.8 ± 6.1) served as the control group.

To best determine glucose levels of the participants during this study, A1C levels were used as a measure of average blood glucose levels over a three month timeframe. A1C levels provide more useful information than individual blood glucose level analyses for this study while ensuring that short-term increases and decreases in blood glucose levels do not obscure broad changes over time that may result from the dietary change.

RESULTS

At the start of the study, the average A1C levels were determined to be 7.04% ± 0.15 and 5.54% ± 0.10 for the diabetic and control groups, respectively (Table 1). Following the multi-month regimen, the diabetic individuals' A1C levels decreased by 0.91% to an average of 6.0% ± 0.1, with 14 of the 17 diabetic individuals' A1C levels dropping below the 6.5% threshold by the termination of this study (Table 1). Average blood glucose levels were also measured. There was little change in the control group over the course of the study, while the diabetic group's average blood glucose dropped by a total of 26.1 mg/dL, from 144.5 to 118.4 mg/dL (Table 1).

Discussion

Diabetes has been previously considered a lifelong disease with a predicted annual cost of $250 billion in the United States in 2012 (American Diabetes Association, 2013). Even patients undergoing active treatment for type 2 diabetes are at risk of additional complications. In a UK cohort study, insulin therapy was associated with

Table 1. Blood glucose and A1C levels of control and diabetic individuals in this study.

	Average blood glucose (mg/dL)			Average A1C (%)		
Group	**Initial**	**Final**	**Change**	**Initial**	**Final**	**Change**
Control	91.1 ± 3.4	93.0 ± 2.8	1.9 ± 2.1	5.5 ± 0.1	5.6 ± 0.1	0.1 ± 0.0
Diabetic	144.5 ± 6.8	118.4 ± 4.8	-26.1 ± 8.8	7.0 ± 0.1	6.1 ± 0.1	-0.9 ± 0.1

All values are provided as mean ± SEM.

increased risk of cancer and all-cause mortality (Currie, 2013). Even with strict medical management, diabetic patients who deviate from their continual regimens of diet, exercise and medication typically have a grim long-term prognosis and see a progression of their symptoms and a decreasing quality of life. As a result, new therapies that can prevent diabetes, slow its progression, ease disease management, or reverse diabetes symptoms has the potential to improve the lives of millions of people.

This multi-month study focused on maintaining individuals on a paleo diet, consisting of meat protein and vegetables, low glycemic fruit and nuts, supplemented with physician-recommended nutritional supplements. Its main aim was to assess the effects of this diet on the blood glucose levels of diabetic patients, in comparison to normal controls. However, diabetes medication was administered to some patients, in response to A1C-level readings that rose above 6.5%. Nevertheless, the dramatic decrease in diabetic A1C levels after a few months, when compared to these changes in control subjects, demonstrates the potential positive effects of this regimen. As with caloric restriction studies (Lim, 2011), retrospective attempts to discern the benefits of naturopathic supplements (Bradley, 2006), and patient-reported benefits of naturopathic care (Bradley, 2012), longer-term studies will also determine if this reversal is sustained. and if long-term adherence to this modified diet will allow for type 2 diabetic patients to control their conditions with reduced reliance on medications. In addition, these results may indicate potential for future studies that compare these effects with those of conventional treatments for type 2 diabetes (e.g. metformin), or with emerging alternative therapies such as phytochemical compounds.

The results of this study appear to support the benefits of a paleo diet for patients with type 2 diabetes, as previously documented in a pair of two-week long studies (Frassetto, 2013; Masharani, 2015). These studies demonstrated that a paleo-style diet can reduce acid secretions and improve insulin sensitivity within two weeks, when compared to the diet commonly recommended by the ADA. However, studies such as these also face many challenges, particularly those related to patient compliance. This is a particular issue, especially if the regimen in question must be followed as a long-term commitment. On the other hand, the ability to suspend medications will incentivize this treatment as a long-term solution for diabetes for many patients. This leads to another potential challenge in conducting more extensive studies; the availability of subjects with well-controlled type 2 diabetes which may be required to withstand long periods without the use of treatments that could confound their data or necessitate a withdrawal from the study due to the need for emergency care due to sudden spikes in A2C levels (Frassetto, 2013).

Conclusions

These findings represent a critical point in our understanding of diabetes treatment; one at which further studies with larger cohort sizes and expanded designs will need to be completed to determine the viability of this regimen for patients with type 2 diabetes, as above. In general, the authors submit that these encouraging results indicate the potential of our regimen to reduce medication usage and possibly halting or reversing diabetic indicators and symptoms, thus warranting more in-depth study. Given the clear impact of the paleo diet on type 2 diabetes, further investigation into these dietary modifications may also provide additional insights into the onset and progression of type 2 diabetes. Our variation on the paleo diet also includes naturopathic (i.e. Apex) supplements, that may correct nutrient deficiencies in diabetic patients. This is an additional variable that may also need investigating, especially in relation to the rest of the ‘paleo’ regimen, to determine its specific role, if any, in diabetic control. In summary, a paleo diet in combination with these Apex supplements appears to be one the most promising short- and long-term interventions for reversing type 2 diabetes.

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Appendix I

Supplements Used & Their Ingredient Lists

APEX ENERGETICS Supplement FACTS © 2017 Apex Energetics, Inc.

CLEARVITE
Serving size 1 scoop (11.31 g)
Servings per container 42

	Amount Per Serving	%DV
Calories	40	
Calories from fat	5	
Total Fat	0.5 g	<1%†
Sodium	60 mg	3%†
Total Carbohydrates	4 g	1%†
Dietary Fiber	1 g	4%†
Protein	5 g	10%†
Vitamin A (as beta-carotene)	850 IU	17%
Vitamin C (as calcium ascorbate, manganese ascorbate)	125 mg	208%
Vitamin D (as cholecalciferol)	50 IU	13%
Thiamin (as thiamin mononitrate)	2 mg	133%
Riboflavin (as riboflavin 5'-phosphate)	2 mg	118%
Niacin (as niacinamide)	4 mg	20%
Vitamin B6 (as pyridoxal 5'-phosphate)	4 mg	200%
Folate (as calcium folinate)	50 mcg	13%
Vitamin B12 (as methylcobalamin)	75 mcg	1250%
Biotin	75 mcg	25%
Calcium (as calcium citrate malate, calcium ascorbate)	100 mg	10%
Phosphorus (as monosodium phosphate)	8 mg	1%
Magnesium (as magnesium citrate)	50 mg	13%
Zinc (as zinc methionate)	2 mg	13%
Selenium (as L-selenomethionine)	8 mcg	11%
Manganese (as manganese ascorbate)	4 mg	200%
Chromium (as chromium polynicotinate)	43 mcg	36%
Molybdenum (as molybdenum amino acid chelate)	43 mcg	57%
Evening Primrose Oil (seed)	450 mg	*
Inulin	450 mg	*
Medium Chain Triglycerides Oil	250 mg	*
L-Glutamine	240 mg	*
L. Acidophilus	2.3 billion CFU	*

Glycine	120 mg	*
Quercetin (as quercetin dihydrate)	83 mg	*
Rutin (from *Sophora japonica* bud extract)	83 mg	*
Hesperidin (from *Citrus sinensis* fruit extract)	50 mg	*
L-Lysine (as L-lysine monohydrochloride)	50 mg	*
Enzyme Blend (amylase, cellulase, glucanase, protease)	40 mg	*
Milk Thistle Extract (seed)	40 mg	*
Taurine	40 mg	*
Marshmallow Extract (root)	30 mg	*
N-Acetyl L-Cysteine	20 mg	*
Choline (as choline bitartrate)	20 mg	*
Jerusalem Artichoke (tuber)	10 mg	*
Gamma Oryzanol	8 mg	*

† Daily Values are based on a 2,000 calorie diet.
*Daily Value (DV) not established.
Other ingredients: Pea protein, natural flavors (chocolate, vanilla), cocoa powder, cellulose, luo han guo fruit extract, stevia extract.

GLYSEN SYNERGY

Serving size 1 packet (4 capsules)
Servings per container 60

	Amount Per Packet	**%DV**
Vitamin C (as ascorbic acid)	100 mg	167%
Vitamin E (as mixed tocopherols)	45 IU	150%
Thiamin (as thiamin HCl)	6 mg	400%
Riboflavin	6 mg	353%
Niacin (as niacinamide, nicotinic acid)	22 mg	110%
Vitamin B6 (as pyridoxine HCl)	2 mg	100%
Folate (as (6S)-5-methyltetrahydrofolic acid, glucosamine salt) (Quatrefolic®)	80 mcg	20%
Vitamin B12 (as methylcobalamin)	4 mcg	67%
Biotin	300 mcg	100%
Pantothenic Acid (as d-calcium pantothenate)	30 mg	300%
Magnesium (as magnesium citrate)	25 mg	6%
Zinc (as zinc glycinate)	4 mg	27%
Selenium (as L-selenomethionine)	16 mcg	23%
Manganese (as manganese aspartate)	2 mg	100%
Chromium (as chromium polynicotinate)	140 mcg	117%

Proprietary Blend: 2810 mg* of Guar Gum, *Gymnema sylvestre* Extract (leaf), *Panax ginseng* Extract (root), Ashwagandha Extract (root), Banaba Extract (leaf), Maitake Mushroom Extract (fruit body), Bitter Melon Extract (fruit), N-Acetyl L-Cysteine, Pectins (apple), Flaxseed Bran (standardized to 4% lignans), Holy Basil Extract (leaf), Enzyme Blend (cellulase, peptidase, glucoamylase, amylase, invertase, maltase), Rhodiola Extract (root), Nopal Cactus Extract (stem), L-Carnitine (as L-carnitine fumarate, L-carnitine L-tartrate), Eleuthero Extract (root), Boerhavia Extract (root), Pantethine, Cellulose Gum, L-Arginine HCl, Alpha Lipoic Acid, Choline (as choline bitartrate), Betaine HCl, *Dioscorea oppositifolia* Extract (root), *Poria cocos* Extract (root), Inositol, PABA, Vanadium (as vanadyl sulfate).

*Daily Value (DV) not established.
Other ingredients: Vegetarian capsule (HPMC), cellulose.
Quatrefolic® is a registered trademark of Gnosis S.P.A. U.S. Patent No. 7,947,662

GLYCEMOVITE
Serving size 1 scoop (10 g)
Servings per container 60

	Amount Per Serving	%DV
Calories	30	
Calories from fat	5	
Total Fat	0.5 g	<1%†
Total Carbohydrates	2 g	<1%†
Dietary Fiber	1 g	4%†
Protein	5 g	10%†
Thiamin (as thiamin mononitrate)	10 mg	667%
Riboflavin	5 mg	294%
Niacin (as niacinamide)	25 mg	125%
Vitamin B6 (as pyridoxal 5'-phosphate)	5 mg	250%
Folate (as (6S) - 5-methyltetrahydrofolic acid, glucosamine salt) (Quatrefolic")	150 mcg	38%
Biotin	50 mcg	17%
Pantothenic Acid (as d-calcium pantothenate)	100 mg	1000%
Calcium (as calcium carbonate)	45 mg	5%
Magnesium (as magnesium carbonate)	30 mg	8%
Manganese (as manganese gluconate)	2.5 mg	125%
Chromium (as chromium polynicotinate)	350 mcg	292%
Potassium (as potassium bicarbonate)	260 mg	7%

Proprietary Blend: 7870 mg* of Pea Protein, Phytosterols Complex (contains beta-sitosterol, campesterol, stigmasterol, brassicasterol), Inulin, Inositol, L-Valine, L-Leucine, L-Arginine (as L-arginine HCl), Pectins (apple), Guar Gum, Cinnamon Extract (bark) (standardized to 8% flavonoids), African Mango Extract (*Irvingia gabonensis*) (seed), Xanthinol Nicotinate, Choline (as choline bitartrate).
†Daily Values are based on a 2,000 calorie diet.
*Daily Value (DV) not established.
Other ingredients: Natural flavor (vanilla), cellulose, luo han guo fruit extract, stevia extract.

Appendix II

Foods Permitted to Subjects during the Study
Daily water (½ your body weight in ounces) and herbal teas.
Fresh fruits (boysenberries, raspberries, blueberries, strawberries, grapefruit, lemon, lime, cherries, pineapple, kiwifruit, starfruit, passionfruit, cantaloupe, guava, apricot, prune, cranberries, dates, clementine)
Vegetables (including celery, carrots, zucchini, cucumbers, avocado, beets, eggplant, asparagus, onion, garlic, spinach, lettuce, butternut squash, cauliflower, broccoli, peppers, yams and sweet potatoes, beans (pinto, black, navy, white, red kidney), and peas (including fresh, split and snap).
Fish (no shellfish), moderate amounts of chicken, turkey and lamb.
Olive oil, coconut oil and avocado oil.
Seeds (sunflower, pumpkin) and nuts (cashews, almonds, pecans, pistachios).
Almond butter, cashew butter, unsweetened almond, coconut milk and cashew milk.
Turkey bacon (nitrate/nitrite and gluten free).
Turkey sausage patties (nitrate/nitrite and gluten free).
Turkey slices
Terra chips and lentil chips (no rice) - there are various flavors.
Stevia, xylitol, dark maple syrup and coconut sugar.

Appendix III

Appendix III vitamin, laboratory values tested for in blood samples taken from all subjects at study initiation and conclusion.

Test Name
Albumin, Serum
Alkaline Phosphatase , Serum
ALT (SGPT)
AST (SGOT)
Bilirubin, Total, Direct and Indirect
BUN and Creatine
Calcium, Serum
Carbon Dioxide, Total
CBC with Differential and Platelet Count
Chloride, Serum
C-Reactive Protein(CRP) High Sensitivity (Cardiac)
Creatine, Serum
Ferritin
Fibrinogen Activity
Glucose, Serum
GGT
Hemoglobin (HGB) A1c
Homocysteine
Iron/TIBC (Total Iron Binding Capacity)
LDH, Serum
Lipid Panel
Magnesium, Serum
Phosphorus, Serum
Citrated Blood
Potassium, Serum
Protein, Total
Sodium, Serum
TSH
Thyroxine, Free (T4,Free)
Thyroxine, Total (T4,Total)
T3, Total
T3, Free
T3 Uptake
Thyroglobulin Antibody
Thyroid Peroxidase Antibody
Uric Acid, Serum
Urinalysis, Routine
Vitamin D, 25- Hydroxycalciferol