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Daniel Sans Graciaa Date

Feasibility of a dietary intervention with a Paleolithic diet-compatible food product

By

Daniel Sans Graciaa
Master of Public Health

Epidemiology

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Michael Goodman, MD, MPH

Faculty Thesis Advisor

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Daniel Sans Graciaa

B.A.
University of Notre Dame
2009

Faculty Thesis Advisor: Michael Goodman, MD, MPH

An abstract of
A thesis submitted to the Faculty of the
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Abstract

Feasibility of a dietary intervention with a Paleolithic diet-compatible food product
By Daniel Sans Graciaa

Objective: Previous trials of the Paleolithic diet have found improvement in metabolic and cardiovascular health indicators. We sought to evaluate the feasibility of using a pre-packaged food product compatible with the Paleolithic diet as a single-meal dietary intervention.

Methods: Healthy volunteers (n=22) replaced their midday meal with 16oz of Chuice, a bottled combination of unpasteurized, unprocessed, raw fruits, vegetables, herbs, nuts and seeds, for 14 consecutive days. The before-and-after comparisons of BMI, blood pressure, heart rate, fasting capillary blood glucose and pulse wave velocity were performed using paired t-tests and Wilcoxon related sample signed-rank tests.

Results: A total of 21 participants completed the study (95% adherence to the protocol). Pulse wave velocity decreased on average by 0.56 m/s with a 95% confidence interval between 0.00796 and 1.1063, and p values of 0.047 and 0.037 for paired t-test and Wilcoxon related samples test, respectively. There were no statistically significant differences in BMI, blood pressure, heart rate, or fasting blood glucose.

Conclusion: This pilot study suggests that the protocol is feasible, participants tolerate the intervention, and, based on preliminary findings for pulse wave velocity, a full-scale, controlled study is warranted.

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Background

Noncommunicable diseases account for an estimated two out of every three deaths worldwide, with one in four deaths attributable to ischemic heart disease and stroke (1). In addition, diabetes, another major non-communicable condition leads to 8.2% of annual all-cause mortality and 11% of the economic costs incurred by healthcare systems and individuals (2). Whereas treatment of these conditions has improved, comparatively little progress has been made with respect to prevention (3-6). It is important to point out that both atherosclerotic cardiovascular disease and type 2 diabetes are thought to reflect the multifactorial metabolic syndrome, which in turn is closely related to nutritional and other lifestyle factors (7-9). For this reason, it is expected that success in preventing chronic metabolic syndrome-related conditions can be achieved following changes in the modern Western diet (10-13).

Compared to traditional or preagricultural diet, the common modern diet involves increased consumption of dairy, grains, salt and various processed foods (14). These foods, when consumed regularly, have been associated with impaired glucose metabolism, high blood pressure, obesity, hyperlipidemia, arterial stiffness, and other pathophysiologic changes that lead to chronic disease (15-20). Studies of diet and health now commonly examine dietary patterns rather than individual nutrients (21-23). This approach uses *a priori* considerations to assess adherence to certain dietary routines with an understanding that nutrients are consumed together and intake of certain types of food, such as fish, may be less important than non-intake of other foods, such as red meat (24, 25). This is illustrated by the successful clinical trial of the Mediterranean diet as an intervention for the prevention of cardiovascular disease (26). Other examples of dietary

patterns that may serve as possible ways to improve metabolic health include Dietary Approaches to Stop Hypertension (DASH), vegetarian, and Paleolithic diets (21, 27).

Sometimes known as a hunter gatherer diet, the Paleolithic diet includes ingredients that have little to no processing, such as meat, eggs, fruits, vegetables, nuts, and seeds while excluding grains, cereals, dairy products, legumes, and refined salts, sugars and oils (28). Previous studies of the Paleolithic diet have found improvement in metabolic indicators even with short interventions and have shown it to have superior efficacy in improving glycemic control compared to both the traditional diabetic diet and the Mediterranean diet (29-32). Evidence also suggests that the Paleolithic diet is effective in decreasing fasting blood glucose in healthy patients as well as those with impaired glucose metabolism or overt type 2 diabetes mellitus (30, 32).

Study Rationale

Despite knowledge of healthy dietary practices, adherence to a prescribed diet is challenging, even in a controlled trial environment (33, 34). Previous trials of Paleolithic-type diets have varied in their delivery of the intervention. Most have provided education and written guidelines to study participants, encouraging consumption of lean meat, fish, fruit and vegetables while excluding dairy, cereal, legumes and sugar, which requires relying on the participants to follow the intervention diet themselves (29-31). One trial provided prepared Paleolithic diet meals to participants (32); this approach ensures a more uniform exposure, but its implementation is logistically complicated, resource-consuming, and may not be feasible in large trials. Recent studies have examined whether food products may provide the benefits of a

healthy diet using more convenient delivery methods, such as pre-packaged ready-to-use meals (35-37). The food product Chuice is a bottled combination of unpasteurized, unprocessed, raw fruits, vegetables, herbs, nuts and seeds that is compatible with a plant-derived Paleolithic diet (Table 1). Unlike the typical Paleolithic diet, however, Chuice includes no animal protein (38, 39). If effective as a dietary intervention, Chuice and similar products might make it easier to incorporate improved nutritional practices into a person's lifestyle. The present study is a short feasibility trial of Chuice as a single meal replacement dietary intervention. If shown to be feasible and well-accepted by study participants, the trial can be expanded to assess efficacy of Chuice in improving glycemic control and other metabolic indicators.

Methods

In this pilot trial, participants replaced their midday meal with a 16 oz bottled serving of Chuice for 14 consecutive days. As Chuice is not pasteurized, it must be refrigerated and has a shelf life of 4 days. One bottle of Chuice was provided to each participant at the study site at noon each day except on days 5 and 10, when two additional bottles were provided, one for each weekend day. Participants consumed as much of the daily Chuice serving as desired and returned the bottles, which were weighed to measure the amount of product remaining.

This study received approval from the Emory University Institutional Review Board (protocol #IRB00065449) and participants completed informed consent. Eligible participants were men and women ages 30-70 years who agreed to present to the study site at noon daily for two weeks and had access to refrigeration on weekends. Exclusion criteria were a previous diagnosis of diabetes mellitus or self–reported criteria for diabetes (fasting plasma glucose $\geq$126 mg/dL, random plasma glucose $\geq$200 mg/dL, or Hemoglobin A1c >6.5%), known allergies to any ingredients of the study product, any immunocompromised status due to primary medical illness or secondary to medications, any medical condition that is a contraindication to dietary interventions such as chronic kidney disease, and any previous steroid use within the previous 6 months. Women who were pregnant or nursing or intended to become pregnant during the study period were also considered non-eligible. Flyers were posted to invite potential study participants to attend an information session where they were provided a sample of Chuice.

Participants came to a baseline study visit having fasted for at least 8 hours; height (in), weight (lbs), heart rate (beats per minute), blood pressure (mmHg), fasting

capillary blood glucose (mg/dL) and pulse wave velocity (m/s) were measured. Body mass index (BMI) was calculated from the measured height and weight. Blood pressure was measured twice in the same arm with a manual sphygmomanometer after 10 minutes at rest. Capillary blood glucose was measured twice for each participant using a finger-stick blood sample and glucometer. Carotid-radial pulse wave velocity was measured using an automatic computerized method with subjects in a supine position. All health indicator measurements were repeated on the day after the 14 day intervention at the same time of day as the baseline measurements. Participants completed a 24 hour food record on the Thursday and the Sunday before the first day of the intervention, each Thursday and Sunday during the intervention and on the Thursday and the Sunday after the intervention ended.

Statistical analyses involved calculations of mean before-and-after differences for each endpoint of interest accompanied by 95% confidence intervals (CI). Baseline and follow-up values of the biometric endpoints were compared using paired t-tests and Wilcoxon related sample signed-rank tests. All statistical analyses were carried out using SAS 9.2 statistical software.

Results

A total of 22 participants completed informed consent and enrolled in the study (Table 2). One participant withdrew from the study before completion of the intervention and did not present for follow-up measurements. The remaining 21 participants completed the study. As shown in Table 2, the age of participants ranged from 30 to 58 years with a mean of 41.3 years. Two thirds of the participants (n=14) were females. With respect to race/ethnicity, the study subjects included 12 (57%) whites, 5 (24%) blacks and 4 (19%) Asians.

Table 3 lists pre- and post-intervention values of health indicators for each study participant. At baseline, mean fasting blood glucose was 87.6 mg/dL (range 74-109). The mean BMI was 27.6 kg/m^2 (range 19.6-42.4); 7 participants (33%) had normal BMI, 8 (38%) were overweight (BMI 25-29.9) and 6 (29%) were obese (BMI $\geq$ 30). Baseline mean systolic and diastolic blood pressures were 111 mmHg (range 89-132) and 73 mmHg (range 58-90) respectively. Mean heart rate was 64 bpm (range 50-88) and mean pulse wave velocity was 6.97 m/s (range 3.5-9.3).

At follow up, mean fasting blood glucose was 83.2 mg/dL (range 44-103). The mean BMI was 27.6 kg/m^2 (range 19.2-42.4). Blood pressure had a mean of 113 mmHg systolic (range 98-137) and 76 mmHg diastolic (range 60-88) with a mean heart rate of 62 bpm (range 46-78). Mean pulse wave velocity was 6.41 m/s (range 5.1-8.0).

As shown in Table 4, pulse wave velocity decreased following intervention by a mean of 0.56 m/s (0.01, 1.11) with a p-value of 0.047 based on a paired t-test, and a p-value of 0.037 based on a Wilcoxon signed-rank test for related samples. From baseline to follow-up, there were no statistically significant changes in fasting blood glucose, with

a mean decrease of only 2.0 mg/dl (95% CI -3.78, 7.72). The mean pre-post intervention differences (95% CIs) were -0.05 kg/m^2 (-0.20, 0.11) for BMI, -2.0 mmHg (-7.51, 3.51) for systolic blood pressure, -2.81 mmHg (-6.40, 0.78) for diastolic blood pressure, and 1.65 bpm (-2.00, 5.30) for heart rate. With the exception of the results for pulse wave velocity, none of the observed differences were statistically significant (Table 4).

In general, participants consumed the entire 16 oz serving of Chuice each day. During the first four days of the intervention, there were 8 unfinished servings (out of 84 total) with mean remaining volume of approximately 4 oz and one missed serving each on days 5 and 6. However, from day 8 through day 14, every serving was consumed in its entirety.

Discussion

In this pilot study with healthy adult participants, we sought to test the protocol for and adherence to a dietary intervention consisting of two weeks of once-daily meal replacement with a plant-based Paleolithic diet compatible food product. There was good adherence, as out of 22 enrolled participants, 21 (95%) completed the study and the majority of servings were completely consumed. Participants generally reported that they enjoyed using Chuice as a meal replacement, though some felt they needed to eat again not long afterwards.

This study was designed as a feasibility assessment and statistically significant changes in outcome measures were not anticipated. Nevertheless, we did find a statistically significant post-intervention decrease in pulse wave velocity. The observed decrease in pulse wave velocity (0.56 m/s on average) is noteworthy because an increase of pulse wave velocity by 1 m/s is reported to be associated with over 10% elevation in risk for cardiovascular events, cardiovascular mortality and all-cause mortality (40). The result for fasting blood glucose, although not statistically significant, was in the hypothesized direction. In contrast, the non-significant increases in BMI and blood pressure were not consistent with the hypothesis.

The observed effect of the intervention on pulse wave velocity may be due to a decrease in inflammation since chronic inflammation contributes to arterial stiffness in humans and the Paleolithic diet has been associated with a decrease in inflammatory markers in animal studies (16, 41, 42). Our findings are consistent with previous short trials of Paleolithic diet in healthy volunteers. Frassetto, et al. found an improvement in arterial stiffness using the marker of arterial distensibility after an intervention with high

potassium and fiber diets for 7 days followed by 10 days of a standardized Paleolithic-type diet (32). The intervention also led to improvements in blood pressure**,** plasma insulin levels, insulin sensitivity and blood lipids. In another three-week trial of Paleolithic diet, Osterdahl, et al. delivered dietary guidelines via seminar and written materials and evaluated adherence to the diet using food diaries. The intervention produced decreases in BMI, waist circumference, systolic blood pressure and plasminogen activator inhibitor-1 but did not change heart rate, fasting blood glucose, glucose tolerance, plasma lipids, C-reactive protein, fibrinogen, or homocystein (31).

Unlike previous trails that tested complete Paleolithic diet interventions of at least three-week duration, our study lasted only two weeks, replaced just one meal a day with the intervention, and otherwise allowed the participants to eat their regular diet.

Two other trials examined Paleolithic diet in participants with chronic health problems. In 13 participants with type 2 diabetes, Jonsson, et al. found lower HbA1c, triglycerides, diastolic blood pressure, weight, BMI and waist circumference after 3 months on a Paleolithic diet compared to 3 months on a diabetic diet (30). Among 29 patients with ischemic heart disease and either glucose intolerance or type 2 diabetes randomized to Paleolithic or Mediterranean diet for 12 weeks, Lindeberg, et al. found improved glucose tolerance (plasma glucose area under the curve during OGTT) in the Paleolithic diet group, independent of change in waist circumference (29). Together, these experimental studies suggest that a dietary intervention longer than 14 days is likely necessary to observe more pronounced health benefits.

The most notable limitations of the current feasibility study include its short duration, low statistical power and less than optimal endpoints. While pulse wave

velocity is the gold standard index of arterial stiffness, there are many methods of measurement. In future studies, it would be beneficial to use the more commonly studied carotid-femoral method rather than the carotid-radial method, which was used here for convenience as it can be performed without asking the subjects to undress (43). Blood glucose measurements were performed using portable glucometers due to resource limitations. In order to better evaluate the effect of the intervention on glycemic control, future studies should test venous blood fasting glucose or include measures of glucose tolerance and insulin sensitivity. Other possible endpoints may include lipid profile and markers of inflammation and oxidative stress. Most importantly, the effect of Chuice on previously tested and new study endpoints should be examined using a larger sample size, including a control group, and over a longer study period.

In conclusion, this pilot study confirmed that replacing one meal a day with a 16-ounce of serving of Chuice is feasible, and the intervention is well tolerated and well received. In addition, our preliminary data suggest that even a short-term intervention with Chuice may improve health indicators such as pulse wave velocity (and perhaps markers of glucose metabolism), without affecting body weight. A larger, longer study is needed to further evaluate this hypothesis.

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Tables

Table 1. Ingredients and nutritional data of food product "Chuice"

Ingredients: Apples, carrots, pears, water, pineapple, celery, grapes, lemon juice, spinach, brussel sprouts, oranges, limes, kiwi, kale, sweet potato, cilantro, honey, aloe vera, ginger root, mint, basil, pumpkin, sunflower seeds, pecans, walnuts, almonds, rosemary, hemp seeds, chia seeds, flax seeds, sesame seeds, ground cinnamon, cayenne pepper, greens blend (proprietary blend)	
Nutrition facts per 8oz of Chuice*	
Calories	140kcal
Total fat	3 gr.
Saturated fat	0 gr.
Trans fat	0 gr.
Cholesterol	0 gr.
Sodium	45 gr.
Total Carbohydrate	28 gr.
Dietary Fiber	5 gr.
Sugars	17 gr.
Protein	3 gr.
Vitamin A	130%[§]
Vitamin C	70%[§]
Calcium	6%[§]
Iron	6%[§]

* Participants were provided 16oz of Chuice,

[§] Percentage represents proportion of daily recommended dose

Table 2. Baseline characteristics of study participants

Age, years		
Mean (range)	41.3	(30-58)
Sex, N (%)		
Female	14	(67)
Male	7	(33)
Race, N (%)		
Black	5	(24)
White	12	(57)
Asian	4	(19)
BMI, N (%)		
Normal	7	(33)
Overweight	8	(38)
Obese	6	(29)

Table 3. Outcome data for all participants completing the study

Subj.	Height (in)	Weight (lbs)		BMI		Systolic pressure (mmHg)		Diastolic pressure (mmHg)		HR (bpm)		Blood glucose (mg/dL)		Pulse wave velocity (m/s)	
		Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
1	64	218	222.5	37.4	38.2	132	110	82	72	64	72	84	78	7.4	5.9
2	70.5	148	149	20.9	21.1	92	100	64	70	56	54	88	65	6.8	5.8
3	63	170.5	170.5	30.2	30.2	110	120	70	80	66	60	93	81	7.7	7
4	65	118	115.5	19.6	19.2	92	100	64	78	58	60	81	83	5.7	6.6
5	68	166	167	25.2	25.4	108	110	79	70	-	60	102	96	6.2	7
6	69	165	163	24.4	24.1	100	100	78	74	50	54	105	102	5.6	5.7
7	68	166	165.5	25.2	25.2	108	105	68	80	52	60	90	74	7.4	7.1
8	69	190	188.5	28.1	27.8	108	120	74	80	56	54	79	71	7.2	6.1
9	61	170.5	169	32.2	31.9	104	120	68	80	61	60	77	71	5.5	8.0
10	63.5	177	177.5	30.9	30.9	110	120	88	80	59	46	101	100	6.9	6.4
11	69	172.5	173.5	25.5	25.6	104	101	58	64	58	54	83	71	3.5	5.2
12	65	254.5	255	42.4	42.4	130	122	78	86	80	70	89	96	8.0	6.1
13	70	205.5	208.5	29.5	29.9	122	122	90	88	75	78	82	100	6.1	5.1
14	65	123.5	125.5	20.6	20.9	102	100	68	79	60	64	75	96	6.4	5.7
15	60.25	169	165.5	32.7	32.1	124	119	84	79	60	68	97	103	8.5	7.9
16	83	232.5	234	23.7	23.9	118	137	70	70	70	70	79	98	9.3	7.4
17	66	172	174.5	27.8	28.2	118	121	78	80	84	74	74	67	7.3	6
18	67	154	155.5	24.1	24.4	104	100	66	60	56	60	79	72	8.0	5.8
19	62	158.5	161	29.0	29.4	89	118	64	78	66	60	109	89	7.9	7.7
20	73	179.5	178.5	23.7	23.5	128	120	78	80	88	66	94	90	7.5	5.8
21	64	153.5	151.5	26.3	26.0	118	98	68	68	54	56	78	44	7.5	6.4
Mean				27.6	27.6	110.5	112.5	73.2	76	63.7	61.9	87.6	83.2	6.97	6.41

Table 4. Mean differences and statistical comparisons of biometric outcomes before and after meal replacement with Chuice

Variable	Mean difference	95% CI		T-test p-value	Wilcoxon p-value
Blood glucose	2.000	-3.7181	7.7181	0.4741	0.356
Pulse-wave velocity	0.5571	0.00796	1.1063	0.0471	0.037
Body mass index	-0.0453	-0.2020	0.1114	0.5535	0.478
Systolic pressure	-2.000	-7.5133	3.5133	0.4581	0.456
Diastolic pressure	-2.8095	-6.3955	0.7765	0.1178	0.103