CLINICAL STUDIES OF A VEGETARIAN FOOD DIET MIXTURE

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A vegetarian food mixture when incorporated into a commercially prepared diet can be used as a supplement or in a vegetarian protein-sparing modified fast. A modification of this diet was given to protein-energy deficient malnourished children in Ethiopia, and it reversed their biochemical defects. The soluble or gel-forming fiber in the mixture also gives the product a favorable glycemic index and reduces glycemic excursion as well as fasting blood glucose and insulin levels. This accounts for the improvements seen in glucose tolerance in type II diabetic patients. These results, however, were preceded by a study of the effects of the mixture in improving glucose tolerance in diabetic rats. A clinical study among New Orleans police officers also suggests that this mixture helps people, without much self-motivation, to lose weight.

In 1983, as reported in this journal,[1] an adult man voluntarily fasted for 55 days on water only. At the end of this time, he broke his fast on fruit juices and a vegetarian mixture containing vitamins, minerals, and trace elements, which he called his 4× formula. Without experiencing any major difficulties, only eight days after ending his fast the subject completed a 20-mile jog and a 60-mile walk, after replenishing himself on the 4× mixture and fruit juices.

Specifically, the 4× formula is high in minerals and trace elements, and consists of concentrated extracts and fractions of processed sesame seed, pumpkin seed, sunflower seed, wheat grass powder, alfalfa, acerola, date powder, carob powder, sea vegetation (ie, kelp, dulse), chlorophyll powder, wheat bran extract, and rice bran extract. This formula is a significant component of the vegetarian food mixture used in the case studies reported below.

When the 4× formula is added to a commercial formula not unlike the infant formulas, the protein source of which is soy protein isolate and which have been fortified with methionine, the result constitutes the commercially sold Bahamian Diet. However, this diet is unlike most adult weight-loss formulas used in the protein-sparing modified fast (PSMF) because it is completely vegetarian. The 4× formula also gives to this product a unique fiber blend which accounts for most of its distinguishing features.

CASE STUDIES

Case Study 1

In dietary studies in the experimental diabetic rat that included the addition of fiber in the form of pectin (10%), a slightly improved glucose tolerance test (GTT) was the result.

In view of the impressive testimonies of several diabetic patients who had improved levels of blood glucose, a pilot study was undertaken in the rat. The objective was to see whether feeding the Bahamian Diet would have any beneficial effect on the GTT of diabetic rats, which were made diabetic by IV injection of streptozocin.

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TABLE 1. FEEDING MIXTURE FOR MALNOURISHED CHILDREN

Components	Amount	Calories	Protein (g)
Bahamian Diet (scoop, each 22.4 g)	3	270	33
Vegetable oil (mL)	100	900	—
Table sugar (g)	15	30	—
Whole cow's milk (mL)	200	140	6
Water (mL)	700	—	—

TABLE 2. SUMMARY OF TREATMENT RESULTS IN MALNOURISHED PATIENTS

	Mean (Range)
Total hospital stay (days)	27.1 (15-48)*
Number of days to attain minimum weight	7.6 (8-10)†
Rate of weight gain while on formula (g/d)	42.3 (0-80)‡
Rate of rise of serum protein (g/d)	0.12 (0.05-0.17)**

* Admission to discharge, though most patients had protracted stay because of serious illness.
† Admission weight and nadir weight used for calculation.
‡ Nadir weight to weight at discontinuance of formula.
** Calculated from readings at admission and either initial peak reading or reading at discontinuance of formula.

Seventy-five Sprague-Dawley weanling male rats were studied for a period of one year, which is half the life span of a laboratory rat. Twenty-five were normal controls, fed on a regular Purina Chow diet. Twenty-five were diabetic, fed a Purina Chow diet containing fiber in the form of 10% pectin. Twenty-five rats were made diabetic and fed the Bahamian Diet. The rats were pair-fed. Baseline and weekly body weights, blood and urine glucose levels, and blood insulin and C-peptide were measured. Monthly GTT and hair zinc levels were also recorded. Food intake was measured daily.

The results showed: (1) Rats fed the Bahamian Diet (BD) gained weight more rapidly and maintained a significantly higher weight (almost equal to that of the nondiabetic controls) than rats fed the 10% pectin diet (PD); (2) BD rats required less insulin for the maintenance of their blood glucose within normal limits than PD rats; (3) hair zinc levels of BD rats were near normal whereas those of PD rats were suboptimal in 25% and deficient in 75%; and (4) GTTs of BD rats were significantly improved when compared with PD rats, and their insulin requirements were much less for the same body weight and food intake, in terms of calories, than those of PD rats. In conclusion, the foregoing observations were statistically significant, indicating a clear beneficial effect of the BD in diabetic rats.

Case Study 2

Advanced protein-energy malnutrition (PEM) occurs commonly in children between the ages of 1 and 5 years in developing countries. In Ethiopia, it is estimated that about 10% of children in this age group are affected. Kwashiorkor and marasmic kwashiorkor comprise about half of those cases. Appropriate management is provision of energy, protein, and other nutrients in a food mixture that is easily digestible, available, and acceptable. The most common food mixture used employs cow's milk to which extra sources of protein (usually cow's milk protein concentrate), energy (vegetable oil), and other nutrients (particularly potassium and magnesium) are added.

Various food mixtures have been tried, and all have some drawbacks, such as cost, availability, and quality of nutrients. In times of famine, the number of cases with advanced PEM dramatically increases and cost becomes an important factor. A modification of the Bahamian Diet is potentially advantageous because it can be produced very cheaply in Africa, and can therefore be made available to a much larger population group. This study reports the results of dietary rehabilitation of malnourished children, using a modification of the Bahamian Diet.

At admission to the study group, a detailed medical, dietary, and social history of each patient was taken and a complete physical examination was performed. Body weight and total serum protein and hematocrit were determined every other day. Antibiotic and supportive therapy were provided whenever needed. The feeding mixture was prepared as shown in Table 1.

One patient died a week after the trial was started. This was a 21-month-old child admitted for kwashiorkor and sepsis, and the malnutrition responded to therapy. This was evidenced by assessment a day prior to her death, when the edema had started resolving, and total protein had increased from 4.5 to 4.8 g%. All the other patients showed uncomplicated clinical improvement and progressive well-being, and dramatic biochemical gains. A summary of the treatment results in surviving patients (mean values and ranges) is shown in Table 2.

One means of testing the nutritional quality of a particular food mixture is to assess the extent to which it successfully reverses the clinical and biochemical changes in children with kwashiorkor. The success in dietary rehabilitation is related to the quality of food consumed.

The modified Bahamian Diet reversed the clinical and biochemical features in all nine children with kwashiorkor or marasmic kwashiorkor, despite the fact that the majority had associated complicating conditions such as infections. Infections are known to increase the energy and protein requirements in a child.

The modified mixture is as good as the standard kwashiorkor mixture, which is made up of cow's milk, calcium caseinate, and oil. The results of this study indicate that the modified Bahamian Diet has a place in the management of children with kwashiorkor. If produced in Africa, its low cost should enable widespread use, thus ensuring adequate coverage of children with protein-energy malnutrition.

Case Study 3

New Orleans police officers participated in an Officers for Fitness program (OFF) in an attempt to lose weight and to get in better physical shape. The reports show that a total of 867 lb was lost by 89 persons who participated in the program from one to ten weeks. This is an average of 9.74 lb lost per person. Averages, however, mask the individual variations, as persons who lose less weight depress the average and offset the success of others.

Of the individuals who approached the goal weight loss, 17 can be classified as successful by losing ≥15 lb while they participated in the program. Goals had been set for subjects to lose approximately 2 lb per week, a moderate amount that would make dieting easy while new eating habits were being learned. Among these successful persons, seven lost more than anticipated, that is, they lost over 20 lb each, and two persons lost over 30 lb. Only three persons are considered program failures, each losing less than 5 lb during the ten weeks of program participation.

The subjects were randomized into three groups. Group A was placed on the General Foods Set-Point Diet with a placebo and taught to use exchanges. Group B followed the same diet, using exchanges, and also received six capsules daily of borage oil containing 20% gamma linolenic acid (GLA). Group C received two servings of the Bahamian Diet daily, in addition to following the Set-Point Diet and using exchanges. All groups were offered a chance to participate in aerobic exercises several times a week. All the women were encouraged to restrict their caloric intake to 1,200 calories per day; all the men were encouraged to restrict theirs to 1,500 calories per day. All groups were offered lectures, one hour per week for a total of ten weeks, covering topics such as behavior modification, stress management for police officers, exercise, smoking cessation, and alcohol and drug abuse.

Weight changes were measured in those who participated for fewer than four weeks; between four and nine weeks; and for the full ten program weeks. Of those who dropped out before completing fours weeks, Groups A and C lost an average of approximately 4½ lb while those in Group B lost less than 3 lb (Figure 1). In these subjects, motivational levels were presumably not adequate for full participation. Previous research on weight control indicates that most dropouts take place during the first month of a program.

Of the 22 participants who dropped out between weeks 4 and 9, the largest average weight loss was obtained in Group C. In that group, five individuals lost an average of 11½ lb, that is, over 2 lb per week. The weight loss performance in the two other groups was lower than expected, with Group B subjects losing about 1 lb per week and Group A subjects doing slightly better.

Finally, of the 22 individuals who completed the ten-week program, the greatest number were in Group C. The greatest average weight loss was found in Group B: 16.8 lb, or better than 1½ lb per week.

Case Study 4

The Type II Adult Onset Diabetes Protocol was another parallel group study of the comparative effects of two diets, the Bahamian Diet versus the American Diabetes Association (ADA) diet, on weight loss, glucose metabolism, and related measures.

Patients were eligible if they (1) were older than 18

TABLE 3. DESCRIPTION OF TREATMENT GROUPS

Patient Identification Number	Age (yr)	Sex	Race	Height (in)	Weight (lb)
Bahamian Diet*					
2	61	F	Black	61.00	184.00
16	46	F	Black	60.50	248.00
17	58	F	Black	63.00	192.00
19	50	F	Black	66.00	315.00
24	69	F	Black	62.00	227.50
26	59	F	Black	64.00	217.50
27	59	F	Black	64.75	250.00
28	47	F	Black	61.00	177.00
29	61	M	Black	70.00	226.00
30	50	F	Black	66.00	163.75
American Diabetes Association Diet†					
6	71	F	Black	68.00	198.75
7	39	F	Black	65.00	180.25
8	63	F	White	59.00	188.25
9	54	F	White	63.00	184.00
14	66	F	Black	62.00	223.00
18	66	F	Black	67.50	241.00
20	49	F	Black	61.75	145.00
21	56	M	Black	65.50	256.00
23	70	M	Black	69.25	192.00
25	56	F	Black	59.00	172.00

* Mean ± SD: Age 56.0 ± 7.41; height 63.8 ± 2.97; and weight 220 ± 79.09
† Mean ± SD: Age 59.0 ± 10.12; height 64.0 ± 3.64; and weight 198 ± 67.94

years of age; (2) had a history of noninsulin-dependent diabetes mellitus of at least three months' duration; (3) had maintained a stable body weight for three months or more; (4) weighed 120% or more of their ideal body weight for their age; and (5) had untreated fasting blood sugar greater than or equal to 140 mg/dL or postprandial glucose greater than 200 mg/dL.

Patients enrolled in the study were required to make weekly visits to the Clinical Research Center Clinic in New Orleans for four consecutive weeks. The first week provided baseline measurements for later comparisons. For each visit, the patients arrived after an overnight fast of at least 12 hours. After recording body weight and obtaining a fasting blood sample, each individual's normal oral hypoglycemic dose was administered, followed in one half hour by the morning meal. Patients in the study group received one scoop of Bahamian Diet in a glass of unsweetened fruit juice, while the ADA group received a standardized 200-calorie meal. The ADA meal was comparable to the study meal in fat, carbohydrate, and protein composition. Additional blood samples were obtained both one and two hours after eating. All plasma samples were analyzed for concentrations of glucose and for insulin levels, the latter by the radioimmunoassay method.

Thirty patients were enrolled; the summary report is based on the 20 who completed the study. All patients in one group were maintained on 1,500 calories, ADA diet, and in the second group on 1,500 calories with two daily servings of the Bahamian Diet in unsweetened fruit juice. Subjects were kept on these diets for four weeks. All but one patient lost weight. Statistical calculations were performed by BMDP.

The two treatment groups are described in Table 3. Only three men participated in the study (one received the Bahamian Diet and two received the ADA diet), and only two whites (both women) participated, both receiving the ADA diet. The two groups were, however, comparable with respect to age, height, weight, sex, and racial distribution.

The average reductions reported in Table 4 indicate that at the end of four weeks, those on the ADA diet had

TABLE 4. AVERAGE REDUCTIONS AT THE END OF FOUR WEEKS

Diet	Weight	Glucose Fasting Levels	Glucose 1 hour	Glucose 2 hours	Insulin Fasting Levels	Insulin 1 hour	Insulin 2 hours
American Diabetes Association	4.25	46.6	63.1	61.1	11.1	21.0	17.8
	(2.27)*	(22.0)	(23.1)	(24.9)	(19.8)	(20.9)	(21.9)
Bahamian Diet	5.72	15.8	82.1	82.3	20.3	13.9	39.0
	(2.60)	(33.2)	(31.4)	(33.2)	(40.4)	(13.6)	(42.2)

* Numbers in parentheses are the percentage losses.

TABLE 5. AVERAGE HOURLY INCREASES FROM FASTING LEVELS

Week	Hour	Glucose: American Diabetes Association Diet	Glucose: Bahamian Diet	Insulin: American Diabetes Association Diet	Insulin: Bahamian Diet
1	1	60.8 (28.7)*	33.2 (14.5)	43.8 (77.7)	51.8 (103.3)
	2	32.9 (15.5)	18.9 (8.3)	24.9 (44.1)	42.4 (84.6)
2	1	41.2 (20.5)	45.5 (24.9)	38.2 (72.6)	50.9 (153.7)
	2	24.9 (12.4)	35.9 (19.6)	24.3 (46.2)	32.3 (97.3)
3	1	37.4 (20.0)	41.5 (22.4)	42.3 (96.1)	63.8 (195.9)
	2	10.2 (5.5)	28.7 (15.4)	33.1 (75.2)	33.6 (103.1)
4	1	44.3 (26.8)	26.9 (17.6)	33.9 (75.0)	58.2 (194.8)
	2	18.4 (11.1)	12.4 (8.1)	18.3 (40.4)	23.7 (79.3)

* Numbers in parentheses are the percentage increases.

lost 4.25 lb whereas those on the Bahamian Diet had lost 5.72 lb on the average. These represent average percentage losses of 2.27 and 2.60, respectively. The pattern of weight loss over the four-week period was 4 lb, 4.43 lb, and 4.25 lb for those on the ADA diet, and 3.53 lb, 4.80 lb, and 5.73 lb for those on the Bahamian Diet. It appears that for persons on the ADA diet there was no appreciable loss in weight after the first week, suggesting that most of this weight loss was due to water loss.

The differences between the performance of the two diets were more marked in connection with the reduction in glucose and insulin concentration (Table 4). The ratio of percentage reductions, Bahamian Diet to ADA diet, is approximately 3:2 for glucose and 2:1 for insulin. These ratios are consistent for the fasting, one-, and two-hour levels, except for the one-hour levels of insulin where those on the Bahamian Diet had 13.6 percent reduction. The average hourly increases from the fasting levels are presented in Table 5; the changes over the observational period are depicted in Figures 1 and 2. Whereas the curves for both diets show obvious downward trends, the curve for the Bahamian Diet is consistently steeper in the first week, showing that the reduction in the stable levels of glucose and insulin are achieved at a faster rate for those on the Bahamian Diet than for those on the ADA diet.

A formal statistical test on this repeated measures design leads to the conclusion that the Bahamian Diet is at least equivalent to the ADA diet in performance regarding body weight ($P=0.41$), and better than the ADA diet with respect to the changes in plasma glucose ($P=0.006$) and insulin ($P=0.059$). Because the study included only three men and only two whites (both of whom were female and received the ADA diet), a question about the results' applicability to men and whites remains. However, for black women, the Bahamian Diet is, on the basis of these data, at least equivalent in performance to the ADA diet and may therefore be recommended.

This diet is valuable because of its unique fiber blend, particularly its soluble or gel-forming fiber component. Whereas the Food and Drug Administration (FDA)

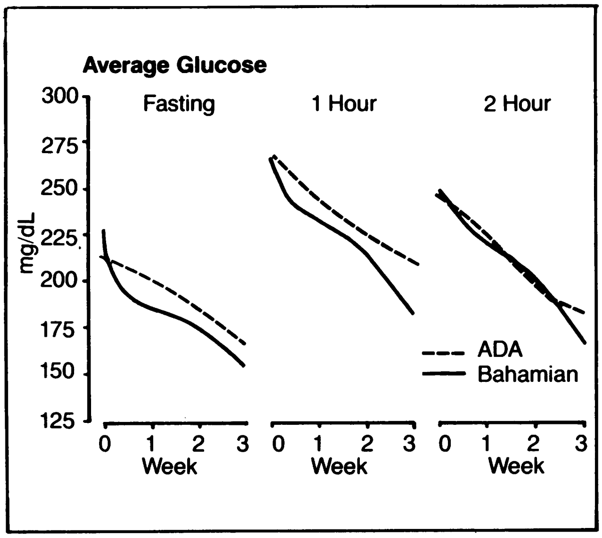

Figure 1. Fasting and postprandial blood sugar levels over three-week period in type II diabetics on the American Diabetes Association (ADA) diet and the Bahamian Diet.

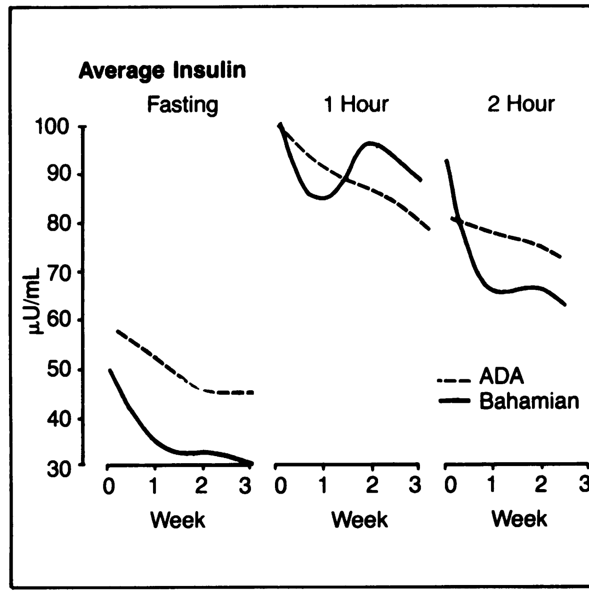

Figure 2. Corresponding fasting and postprandial insulin levels in type II diabetics on the American Diabetes Association (ADA) diet and the Bahamian Diet over a three-week period.

"does not consider the additional intake of 'dietary fiber' provided by the use of the product, in the amount of 389 mg per serving or 778 mg per day, to be significant," the FDA is apparently basing its opinion on the amounts of undigested material left after combustion, or chemical or enzymatic digestion. This material, although it may correlate with the amounts of bran or insoluble fiber in a food or diet, may bear little or no relationship to the amount of soluble or gel-forming fiber, and it is not in any way indicative of the physiologic effects during transit through the gastrointestinal tract.

The value of a diet high in fiber and complex carbohydrates has been debated by Reaven[2] and Wood and Bierman.[3] They tried to determine whether the diabetic diet should be high in complex carbohydrates and low in fat, or whether diabetics should avoid carbohydrates as much as possible and restrict lipids to mono- and polyunsaturated fat.

Reaven stated that the "objective in type II diabetes should be to get the LDL cholesterol as low as you can. The specific lipid defects you see in type II diabetes are a high VLDL, TG, LDL cholesterol, and a low HDL cholesterol." He advocated a diet that is moderate, not high, in carbohydrate content and lower in saturated fat. Eating more mono- and polyunsaturated fat can lower LDL without exacerbating the defects in VLDL and HDL.

In the opinion of Wood and Bierman:

> The diet should be reduced in total fat, saturated fat, and cholesterol. The reduction in saturated fat is usually accompanied by a compensatory increase in carbohydrate, polyunsaturated and monounsaturated fat. Epidemiological studies suggest that there are no harmful effects from following a diet where the saturated fat has largely been replaced by complex carbohydrate . . . . The concern for raising triglycerides and lowering HDL levels in diabetics is based on short-term metabolic studies. In the short-term studies, fasting levels of triglycerides do go up when carbohydrates are substituted for fat, usually within the first 24 hours, or until a new equilibrium is established.

Diets high in fiber, such as those used by Anderson and Gustafson,[4] are unpalatable. Furthermore, in their studies Anderson and Gustafson consistently modified or changed two variables at the same time. Whenever they changed the fiber intake they also changed the insulin level.

The work of Mann[5] in Oxford, England, however, is creditable. The problem with his diet is that 45% of the calories come from legumes; legumes, plus margarine, skim milk, and whole wheat bread, constitute 85% of the entire daily caloric intake. This does not even vaguely resemble a "normal" diet.

A recent publication by Zavaroni et al[6] shows that persons with abnormal oral glucose tolerance are hyperinsulinemic, as well as hypercholesterolemic and hypertriglyceridemic. In addition, they have significantly elevated systolic blood pressures and heart rates. The hyperinsulinemia seems to be the driving force for most of these abnormalities. Resistance to insulin-stimulated glucose uptake is the basic defect. In an effort to overcome the insulin resistance, greater than normal amounts of insulin are secreted. The ensuing increase in plasma insulin levels causes hypertriglyceridemia of hepatic origin, and elevated systolic blood pressure and increased heart rate, possibly through an elevation of catecholamine levels. If it can be shown, as these data suggest, that a vegetarian food mixture containing soluble fiber when taken twice daily reduces blood insulin levels, then that mixture could be a useful dietary adjunct in the management of noninsulin-dependent diabetes.

To get the benefits of soluble fiber, it may have to be given as a supplement to a "normal" diet. The vegetarian food mixture—The Bahamian Diet—described in this article reduces glycemic excursion and has a very favorable glycemic index. It lowers both fasting blood sugar and insulin levels.

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