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The Role of Nutrition in Glycemic Control: Results of a Preliminary Study

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Abstract

Purpose: Nutrition has been shown to have a positive impact on glycemic control. The purpose of this study is examine the effect of proper nutrition on glycemic control, especially blood glucose levels and the percentage of glycated hemoglobin.

Methods: A convenience sample of individuals with diabetes was selected. Study participants with type 1 and type 2 diabetes incorporated planned meals into their diets for a period of ten weeks. Pre-study mean blood glucose levels, variation in mean blood glucose levels, HbA1c values, and body weight was compared to post-study values. Results: After incorporating planned meals into their diets, the majority of study participants had statistically significant reductions in mean blood glucose levels. The reduction in mean blood glucose levels was 35 percent. Participants experienced a 4 percent reduction in glycated hemoglobin percentages. On average, participants had a blood glucose variation of 35.9 percent. Weight loss was seen in 77 percent of study participants.

Conclusions: The study results indicated that incorporation of planned meals and nutritional education has a beneficial effect on controlling blood glucose levels. These results indicate that this study should be replicated with a larger sample size. Use of a convenience sample results in the inability to generalize the study's findings.

Keywords: Diabetes; Weight loss; Glycated hemoglobin; Nutrition; Glycemic control; Prospective study design

Introduction

There exists a great deal of research that suggests that proper nutrition has a significant effect on glycemic control. Blood glucose levels and the variation of these values are directly affected by what someone eats. This effect is seen in people 2 diabetes[1,2]. This paper describes a pilot study of people with diabetes and how incorporating proper nutritionally designed meals into their diets affected their glycemic control.

Type 1 Diabetes

Type 1 diabetes (T1D) is an autoimmune disease, resulting in the loss of ability to produce insulin. The causes of T1D are not known, but diet and lifestyle have no impact on its onset. Type 1 diabetes is seen in both children and adults. It is characterized by rapid onset, no cure, and a lifetime threat of complications.

Approximately 1.25 million people in the United States have T1D, 200,000 children and over one million adults. It is estimated that 40,000 people in the United States are diagnosed with T1D each year[3]. By 2050, it is expected that 5 million people in the United States will have T1D, and 600,000 children[4].

Type 2 Diabetes

Type 2 diabetes (T2D), in early stages does not cause symptoms. Its early development is unknown to the person with diabetes. During its progression, to a point that the person begins to have health problems, T2D is seen as a mild hyperglycemia. These people are said to be pre-di-

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abetic. Hyperglycemia has several symptoms, including high levels of blood sugar, high levels of sugar in the urine, frequent urination, and increased thirst. High blood glucose occurs when the body does not produce adequate amounts of insulin, or the insulin cannot be used by the body (this is called insulin resistance). When a person is found to have mild hyperglycemia they are at risk for developing diabetes and early treatment should begin. This treatment involves patient education, diet and nutrition changes, exercise, and medications. It is estimated that over 22 million people in the United States have mild hyperglycemia. When T2D progresses, medical treatment becomes necessary[5].

T2D can be prevented by proper diet, exercise, and weight loss in obese people. These factors can help to prevent T2D whether they are used alone or in combination. A more profound improvement results if these factors are implemented at the same time. The Malmo Feasibility Study showed that weight loss and improved physical fitness each improved health and prevented the development of T2D. The study also showed that when a weight loss and improved physical fitness program were used together, the improvement in health was doubled[6].

Medications are available for the treatment of T2D, but none assist in its prevention. The medications have been successful in improving insulin resistance for short periods of time, but this improvement is not permanent.

A relatively new approach has shown promise as a treatment for diabetes associated with obesity. The shared medical appointment is a multidisciplinary team approach in a group setting in which nutrition therapy, physical activity, and appetite suppression is addressed. It has been shown that a small weight loss, less than 5%, has significant benefits to the patients, including glycemic control[7]. Shared medical appointments have been shown to be effective in treating patients with obesity[8].

Epidemiology of Diabetes

Diabetes was the seventh leading cause of death in the United States in 2015. This is significant because it is assumed that diabetes may be underreported as a cause of death. Only about 35% to 40% of people with diabetes who die have diabetes listed on the death certificate as a cause of death[9]. Table 1 presents the leading causes of death in 2015[10].

Table 1: Top Ten Leading Causes of Death, U.S., 2015

Cause	Number of Deaths
Heart Disease	614,348
Cancer	591,699
Chronic Lower Respiratory Diseases	147,101
Accidents (unintentional injuries)	136,053
Stroke (cerebrovascular diseases)	133,103
Alzheimer’s Disease	93,541
Diabetes	76,488
Influenza and Pneumonia	55,227
Nephritis, nephrotic syndrome, and nephrosis	48,146
Intentional self-harm (suicide)	42,773

Source: CDC, Health, United States, 2015

Diabetes is associated with several complications and co-morbidities. These include: hypoglycemia, hypertension, dyslipidemia, cardiovascular disease, heart attacks, stroke, blindness, and kidney disease.

Hypoglycemia is responsible for over 300,000 emergency room visits annually. Over 70% of adults with diabetes have blood pressures greater than 140/90 millimeters of mercury or are taking prescribed medications to lower high blood pressure. More than 65% of adults with diabetes have blood LDL cholesterol greater than 100 mg/di or are taking cholesterol-lowering medications. Cardiovascular disease death rates are higher among adults with diabetes. Hospitalization rates for heart attacks are two times higher in adults with diabetes, as well as hospitalization rates for stroke. Over 30% of adults aged 40 years and older with diabetes have diabetic retinopathy, which may result in loss of vision. In 44% of new cases of kidney failure, diabetes is listed as the primary cause[11].

Diabetes incidence and prevalence has been increasing steadily since 1990. According to the Centers for Disease Control and Prevention, 29.1 million Americans have diabetes, or 9.3% of the total population. Of these, 21 million have been diagnosed and 8.1 million diabetes are undiagnosed; 27.8% of people with diabetes are undiagnosed[12]. Table 2 presents information on the prevalence of diabetes of people 20 years and older, by age and gender. Table 3 shows the prevalence by race.
Table 4 presents the incidence of diabetes of those people over the age of 20 years. The incidence rate of diabetes is 7.8 new cases per 1,000 people in the population. The incidence rate is highest in people over the age of 65 years, 11.5 new cases per 1,000 people in the population.

Table 2: Prevalence of Diagnosed and Undiagnosed Diabetes in People 20 years and older, U.S., 2014

Age	Number (in millions)	Percent
20 years and older	28.9	12.3
20-44 years	4.3	4.1
45-64 years	13.4	16.2
65 years and older	11.2	25.9
Men	15.5	13.6
Women	13.4	11.2

Source: CDC, Health, United States, 2015

Table 3: Prevalence of Diagnosed and Undiagnosed Diabetes in People 20 years and older, by Race, U.S., 2014

Age	Percent
Non-Hispanic Whites	12.3
Asian-Americans	9.0
Hispanics	12.8
Non-Hispanic Blacks	13.2
American Indians/Alaska Natives	25.9

Source: CDC, Health, United States, 2015

Table 4: Incidence of Diagnosed Diabetes in People 20 years and older, U.S., 2014

Age	Number	Rate per 1,000 Population
20 years and older	1.7 million	7.8
20-44 years	371,000	3.6
45-64 years	892,000	12.0
65 years and older	400,000	11.5

Source: CDC, Health, United States, 2015

Costs of Diabetes

The costs of diabetes have been increasing every year. In 2014, $14 billion of health care costs in the United States were associated with treatment of type 1 diabetes[13]. The cost in 2017 of T1D and T2D was $327 billion, with $90 million in reduced productivity. This represents about 20 percent of all health care dollars spent on diabetes. Those who are diagnosed with diabetes have annual health care costs of almost $17,000 and 59 percent of costs are directly associated with diabetes care.

Indirect costs associated with absenteeism and reduced productivity were $3.3 billion in 2017 for those people who were employed. Costs related to loss of productivity of those not in the workforce because of diabetes equaled $2.3 billion. Almost 280,000 premature death were due to diabetes, costing approximately $20 billion in lost productivity[14].

The costs of diabetes are manifested in the utilization of health care services. A study of adults 50 years of age and older was conducted to evaluate health care services usage. These services included physician visits, outpatient clinic visits, hospital admissions and emergency department visits. The study determined the average marginal effects on the costs of health care services. The study results showed that people with diabetes experienced one and a half more physician visits annually than those without diabetes. With respect to hospital admissions, people with diabetes had 53 percent more admissions than those without diabetes. People with diabetes visited the emergency department 33 percent more often than those without diabetes[15].

Benefits of Proper Nutrition

Proper nutrition is an important component of the treatment for all people with T1D. Previous studies have shown that nutrition therapy interventions reduce glycated hemoglobin (HbA1c), as well as other beneficial results[16]. It was shown that each patient would benefit from an individualized food plan based on proper nutrition, schedule, and physical activity. In fact, the American Diabetes Association recommends individualized medical nutrition therapy, including education and counseling[17]. Proper nutrition and nutrition education are important in ensuring that the patient and family members understand the impact food has on blood glucose, as well as food interactions with exercise and insulin. A food plan must take into consideration the patient's age, literacy, engagement, and ability to adjust insulin. General diabetes nutrition principles, as defined in the ADA Standards of Care[18], apply to people with T1D, particularly in reference to normal growth and development in youth and the maintenance of a healthy body weight at all ages.

Specifically, education about carbohydrate counting and meal composition should be addressed. For those people with Type 1 diabetes who understand carbohydrate counting, education on the impact of protein and fat on glycemic excursions should be incorporated into diabetes management[19]. People who are overweight or obese may benefit from weight reduction counseling.

Individualized nutrition therapy is recommended for all people with type 1 diabetes as an effective component of the overall treatment plan. Monitoring carbohydrate intake, whether by carbohydrate counting or experience-based estimation, remains a key strategy in achieving glycemic control.

Healthy eating habits are important for management of T2D. The challenge for people with T2D is deciding what to eat. The American Diabetes Association recommends that people with diabetes become actively involved in planning their nutrition needs with their health care providers[20]. A wide range of diets that have been shown to be effective clinically, but there is no ideal recognized nutrition plan[21].

The type of diet planning has been shown to be effective in reducing weight, reducing blood glucose levels, and improving lipid profile which reduces cardiovascular risk in people with T2D. Previous studies have shown that low carbohydrate, low-glycemic index and Mediterranean, and high protein diets improve glucose metabolism[22].

Study Design

The study design was an observational prospective study using convenience sampling. The study participants were clients of a regional diabetes supply company with both T1D and T2D. Initially, forty-four (46) clients agreed to be part of the study, but thirty-five (35) completed the study.

Of the study participants, twenty-eight (28) were Caucasian, six (6) were African-American, and one (1) was Asian. Twenty-three (23) participants have T1D and twelve (12) have T2D. The mean age of all participants was 44.9 years; 42.1 years of age for participants with T1D and 50.2 years of age for participants with T2D. The gender distribution of all participants was 48.6 percent females and 51.4 percent males. Among participants with T1D thirteen (13) are male and ten (10) are female. The gender distribution in participants with T2D was five (5) males and seven (7) females. Table 5 provides demographic information on the participants who completed the study.

Table 5: Pilot Study Participants Demographics

Study Subject	Gender	Age	Race	Type
1	Male	35	White	1
2	Female	40	White	2
3	Male	29	Asian	2
4	Male	71	White	1
5	Female	33	White	2
6	Male	49	White	2
7	Female	37	White	1
8	Male	13	Black	1
9	Male	59	White	2
10	Female	58	White	1
11	Male	31	White	1
12	Female	33	Black	1
13	Male	57	White	1
14	Female	14	Black	1
15	Male	43	White	2
16	Male	67	White	1
17	Female	29	White	1
18	Female	56	Black	2
19	Female	29	White	1
20	Male	63	White	2
21	Male	67	Black	1
22	Female	43	White	2
23	Female	75	White	2
24	Female	25	White	1
25	Male	40	White	1
26	Female	30	White	1
27	Male	26	White	1
28	Female	52	White	2
29	Female	78	White	1
30	Male	42	White	1
31	Male	64	White	1
32	Female	28	White	1
33	Male	40	White	1
34	Female	60	Black	2
35	Male	54	White	1

The study period for each subject lasted ten (10) weeks, with blood glucose levels measured five (5) times daily, as well as pre-study and post-study HbA1c values. The blood glucose levels were measured in the morning, two (2) hours after every meal, and in the evening. Continuous glucose monitoring was used. During the ten (10) week study period, subjects incorporated planned meals into their daily diet for six (6) weeks. Additionally, blood glucose information was collected two (2) weeks prior and two (2) weeks after the ten (10) week study period. This meal planning was not their entire nutrition but consisted of one (1) meal a day four days per week. The planned meals were provided by a national food production company, whose meals replicate the pleasant food experience of taste, texture, appearance, and aroma while reducing (or eliminating) salt, saturated fats, and sugars, as well as many of the added chemicals present in most pre-packaged foods. Some participants purchased additional meals.

The meals were prepared by the food production company, in coordination with registered dietitians and diabetes educators to customize the nutrition for each participant. The meal plan was designed to allow for the adoption of healthy eating habits while managing chronic conditions, as well as post-discharge from hospitals and other health care facilities. This management, under the supervision of health care professionals, is expected to improve health and reduce the risk of hospitalization.

Study Results

Table 6 shows the blood glucose values before the pilot study began. The average (mean) blood glucose levels for the pilot study period are shown for each subject. The variation in blood glucose levels (standard deviation) is also shown. Pre-study blood glucose information was not available for Participant #4. Post-study blood glucose information was not available for Participant #8.

Overall, the pre-study median mean blood glucose was 171.9 mg/dl and the post-study median blood glucose was 143.3 mg/dl. The pre-study median mean blood glucose for participants with T1D was 170.5 mg/dl; post-study median was 144.1 mg/dl. For participants with T2D, the pre-study median mean blood glucose was 177.3 mg/dl and the median post-study was 135.2 mg/dl. The pre-study mean standard deviation for all participants was 54.1 mg/dl, with a post-study mean standard deviation of 39.9 mg/dl, or a 35.9 percent decrease in variation. Those with T1D had a pre-study mean standard deviation of 46.1 mg/dl. The post-study mean standard deviation for participants with T1D was 35.0 mg/dl. This is a 24.1 percent decrease in variability of blood glucose levels in those with T1D. Participants with T2D had a pre-study mean standard deviation of blood glucose levels equal to 56.4 mg/dl, compared to 44.8 mg/dl for participants with T1D. This is a 25.9 percent decrease in the amount of variation.

To determine whether the decreases in mean blood glucose levels were statistically significant, as well as clinical significance, paired t-tests of means were performed. The level of significance was 0.05, with a one-tailed distribution. The results of the paired t-tests are shown in Table 6 for thirty-three of the study participants. There was a statistically significant decrease in mean post-study blood glucose levels in twenty-two (22) participants (67% of the study sample), with p-values ranging from <0.005 to <0.0001. Blood glucose levels decreased on nine (9) other participants, but statistical significance could not be established. So, blood glucose levels clinically significantly decreased in thirty-one (31) of the participants (94% of the study sample).

Table 6: Blood Glucose Values

Study Subject	Pre-Study Mean Blood Glucose Levels	Post-Study Blood Glucose Level	Pre-Study Standard Deviation	Post-Study Standard Deviation	p-values
1	171.6	160.2	58.9	44.4	<0.03
2	206.8	130.3	106.1	20.7	<0.05
3	172.3	180.5	130.3	33.9	<0.001
4		129.1		34.4	
5	120.1	109.7	60.7	57.6	N.S.
6	182.3	144.6	24.0	22.1	<0.0001
7	123.5	101.4	17.8	23.2	<0.001
8	225.6		59.2		
9	232.2	217.5	61.7	55.9	N.S.
10	169.5	147.8	67.5	46.6	<0.05
11	148.9	135.7	41.9	42.8	<0.05
12	183.3	167.8	80.1	63.3	N.S.
13	139.2	130.7	41.6	28.3	<0.05
14	195.5	159.7	77.5	67.1	<0.001
15	200.8	178.2	26.5	45.7	<0.05
16	159.3	133.2	41.9	39.6	<0.001
17	108.4	101.9	35.9	19.8	N.S.
18	117.9	114.3	20.9	20.2	<0.05
19	148.9	140.9	52.4	36.8	N.S.
20	147.7	116.4	47.4	40.6	<0.0001
21	175.8	158.7	49.2	36.2	<0.01
22	183.1	133.1	44.7	25.7	<0.00001
23	114.8	115.3	12.8	12.7	N.S.
24	184.9	142.7	75.2	56.6	<0.01
25	153.9	162.7	65.3	45.1	N.S>
26	197.5	162.1	71.7	55.5	<0.001
27	145.2	135.9	53.9	41.6	N.S.
28	144.4	137.2	40.6	36.1	N.S.
29	163.4	145.4	58.8	40.6	<0.0001
30	200.0	174.0	85.6	65.3	N.S.
31	200.3	185.9	48.6	55.8	<0.05
32	178.0	149.7	71.1	71.0	<0.05
33	227.7	183.3	52.4	49.9	<0.001
34	203.7	143.3	56.84	45.0	<0.001
35	124.8	119.3	51.9	49.9	N.S.

Table 7 shows HbA1c values and weight loss among the study participants. HbA1c values decreased in twenty-six (26) of the study participants (74% of the study sample). The mean reduction in HbA1c among these twenty-six (26) participants was 1.1%. HbA1c decreases ranged from 0.3 percent to 3.4 percent, a reduction of 2.4 percent to 38.2 percent. One (1) participant experienced no change in HBA1c, while eight (8) participants experienced an increase in glycated hemoglobin.

Table 7: HbA1c Values and Weight Loss

Study Subject	Pre-Study HbA1c Value	Post-Study HbA1c Values	Percent Decrease	Weight Loss (lbs)
1	6.9	6.6	4.4	2
2	4.8	5.5	+14.6	3
3	10.2	8.0	21.6	0
4	7.2	6.1	15.3	17
5	9.6	8.6	10.4	10
6	8.9	5.5	38.2	18
7	7.8	7.4	5.1	2
8	9.0	9.6	+6.7	+2
9	8.3	7.7	7.2	10
10	6.8	7.3	+7.4	+3
11	7.2	7.0	2.8	6
12	11.0	9.9	10.0	6
13	7.1	7.2	+1.4	1
14	8.2	6.6	19.5	1
15	7.6	6.6	13.2	2
16	7.8	6.9	11.5	7
17	5.2	5.2	0	+2
18	6.3	5.7	9.5	5
19	6.2	6.3	+1.6	4
20	8.7	6.2	28.7	5
21	6.9	6.2	10.1	+1
22	8.4	5.9	29.8	7
23	8.2	8.0	2.4	6
24	7.6	5.3	30.3	
25	7.9	7.7	2.5	
26	6.1	6.7	+9.8	1
27	8.2	7.6	7.3	0
28	8.2	6.7	18.3	+1
29	6.6	6.3	4.5	1
30	8.3	9.1	+9.6	1
31	10.3	7.7	25.2	4
32	8.1	7.2	11.1	0
33	7.3	8.3	+13.7	2
34	7.6	6.9	9.2	13
35	6.1	5.5	9.9	13

Weight loss was not a primary study objective; however twenty-seven (27) participants experienced a decrease in body weight during the study. The mean of weight loss in pound for these twenty-seven (27) participants was 5.1 pounds. Five (5) participants gained weight, a mean of 1.8 pounds, and weight loss was not recorded for two (2) participants. Participants with T1D experienced mean body weight loss of 2.6 pounds, and those with T2D had a mean weight loss of 6.1 pounds. Female participants averaged 5.8 pounds weight loss. Male participants had a mean weight loss of 6.3 pounds. Male participants with T1D loss an average of 3.5 pounds, while females with T1D had a mean weight loss of 0.9 pounds. Female's participants with

T2D experienced a mean weight loss of 6.1 pounds; males with T2D have a mean weight loss of 6.9 pounds.

Policy Implications

Findings from this study have direct policy implications. Principally, Diabetes Self-Management Education and Support (DSMES) programs are framed by evidence-based standards to aid individuals with managing diabetes[23]. Findings on the nutritional benefits that translate into reductions in blood glucose levels are evidence useful in the development of DSMES plans. While DSMES plans are shown to improve health outcomes, these tools are underutilized. Strengthening of evidence to support improvements in health outcomes could facilitate greater DSMES coverage by private payers. Also, while 92% of states have insurance laws that mandate or require offering of diabetes coverage, 8% have no such policies[24]. Highlighting the health benefits from improved nutrition and related cost reductions to state budgets could influence diabetes coverage mandates in outlier states.

Conclusions and Limitations

The results of the study indicate that incorporation of planned meals and nutritional education has a beneficial effect on controlling blood glucose levels. In 94 percent of study participants, the mean blood glucose levels decreased. HbA1c values decreased in 74 percent in the participants. The cause of the increase in the HbA1c level is unknown but could be related to issues of individual diet compliance or use of home measurement kits. Although weight loss was not a primary focus of the study, 77 percent of participants lost weight.

The study results are very positive and promising for further research. However, the study needs to be scaled up to a sample size which will allow for analysis of the effect of demographics and changes in nutrition, as well as changes in eating behavior. Specific meal plans need study to determine the differential effect, if one exists. Insulin use must be included as one of the study variables.

There are several study limitations. First, the study used a convenience sample. Convenience sampling is a nonrandom method of selection. A convenience sample was used because of the need to recruit participants with diabetes who were willing to participate and the financial means to purchase the meals. Given that participants volunteered, this could result in bias. Second, the convenience sample is not representative of the population of individuals who have diabetes, and the small number of participants does not allow for generalization of study results. Third, the small number of participants does not allow for stratification of data to study the effects of age, race, gender, and other personal variables. Fourth, analysis of behavioral aspects needs a larger sample size to determine if statistically significant effects exist. However, it can be assumed that study subjects have positively changed their eating habits, with respect to portion size and type of foods eaten, as a result of incorporation of planned meals into their diets.

In conclusion, this study has shown that incorporation of planned meals lower mean blood glucose levels. Additionally, the variability of blood glucose levels is reduced when eating planned meals. Results also have shown that HbA1c levels can be expected to decrease when eating nutritionally sound meals.

Compliance with Ethical Standards

Peter Fos served as a paid consultant during the study for data collection and analysis. Peggy Honore' has no conflict of interest.

The study subjects all volunteered and completed an informed consent.

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