A Lifestyle Approach for the Control of Diabetic Hyperglycemia

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Summary

A rise in treated disease prevalence is the most important determinant in the growth of private insurance spending.[1,2] Diabetes and related chronic health conditions – hypertension, dyslipidemia, obesity, and sedentism – are increasing in prevalence and factor heavily in the 70 percent of direct, annual, health care costs that are spent on chronic diseases. Thus, strategies for improving glycemic control can reduce overall medical costs for patients with diabetes.[3]

Presented here is a lifestyle curriculum associated with long-term glycemic control in two case studies.

Key Points

• The first case study presented is an individual who participated in a behavioral adaptation of the Mediterranean diet, resulting in immediate and long-lasting control of hyperglycemia.

• Nutritional analysis of the food record indicates sharp decreases in sodium consumption associated with the alleviation of previously uncontrolled hyperglycemia.

• A follow-up study demonstrated similar and significant reductions in hyperglycemia after participating in the Mediterranean Wellness curriculum. This group participated in the program through a remote delivery model.

A Modified Mediterranean Diet

The Mediterranean diet has been widely acknowledged as being a healthy approach for residents of this region, associated with many aspects of a healthy lifestyle including glycemic control,[5] heart health,[6] and cancer prevention.[7] However, the elements most commonly associated with the Mediterranean diet include the specific foods eaten, as diagrammed in the Mediterranean Food Guide pyramid. Eating behaviors of this diet are equally important and must be included into any effective lifestyle approach.

In these trials, we have modified the traditional Mediterranean diet in two essential ways: in the method of food selection, and in the behavioral habits of healthy eating.

• Food selection is principles–driven, meaning that this curriculum does not specify exact food elements or amounts. Participants do not have to eat according to an accounting of calories, fats, carbohydrates, or proteins. Rather, they are coached according to general principles that accord with the Mediterranean approach. 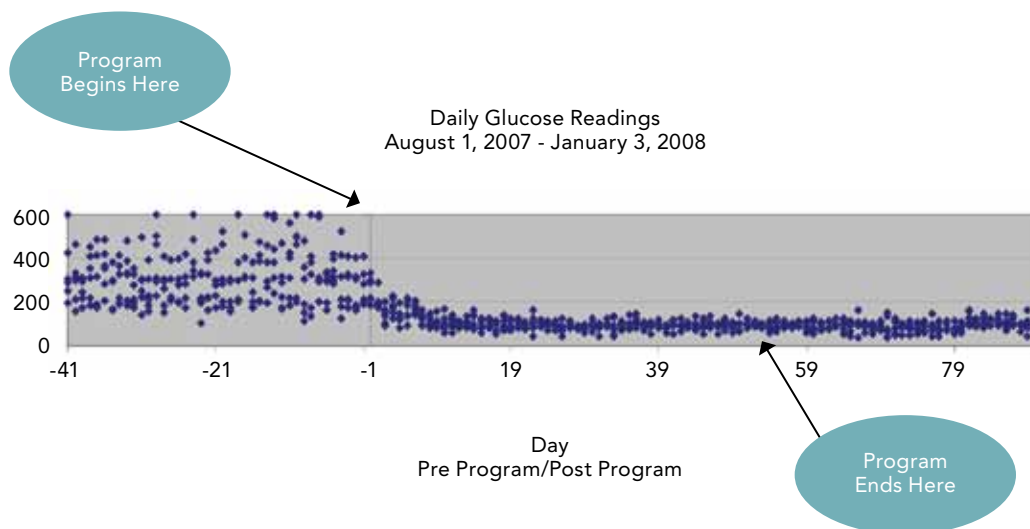Regarding food selection, participants may choose from anything from the Mediterranean food guide pyramid, as long as it does not include artificial or synthetic ingredients. The principle here is to "eat real food".

• In addition to the foods themselves, the behavioral retraining of healthy eating habits is essential to a lifestyle approach to food selection and controlled consumption.[10] To this end, the modification of the traditional Mediterranean diet here incorporates the retraining of healthy eating habits. These include procedures for retraining the microstructure of eating behavior: at the fork, at the bite, portioning, plating, pacing, drinking control, and coaching for specific daily life situations.

Curriculum Delivery Structure

Participants met weekly to receive PowerPoint lectures in the Mediterranean Wellness curriculum, delivered either in person or remotely via webcast. Each week included ancillary supporting materials such as homework, recordings of each lecture for on-demand review offline, recipes, instructional videos,

Exhibit 1: Daily Glycemic Control

Program Begins Here

Daily Glucose Readings
August 1, 2007 - January 3, 2008

Program Ends Here

Day
Pre Program/Post Program

daily audio coaching, and a weekly participant manual. These materials were available in physical form as well as in electronic form on a website platform.

Weekly Curriculum Content
• Week 1: The first week teaches the Mediterranean food guide pyramid, emphasizing the importance of eating natural foods, rather than synthetic processed food products. Participants complete this week capable of making healthy food choices at conventional grocery stores. Homework includes specific lists for replacing poor food choices with healthy food choices and ingredients to include/exclude, along with a method for the habituation of individual tastes for sweetness in foods.

• Week 2: The second week begins training participants in the eating habits and routines that curtail excess consumption. This behavioral protocol includes the use of eating implements, hand-held foods, portioning, drinking, and specific coaching for consumption in a restaurant and home environment. Homework includes behavioral practice routines at each meal, with instructions to compare their volume of consumption to pre-program levels.

• Week 3: The third week reinforces the personal habits learned in Week 2 by teaching participants to control overconsumption through individualized pacing techniques. Emphasized here are the physiological mechanisms of satiety, and their practical manipulation within specific circumstances. Homework includes a quantitative measure of each participant's current appetite levels, with the ability to track changes over time.

• Week 4: The fourth week introduces the eating routines required to control between-meal consumption, and emphasizes a daily three-meal standard for meal consumption. Homework includes at-home trials to quantify and affect phasic hunger in response to these routines.

• Week 5: The fifth week informs participants on the links between stress and weight gain, with emphasis on the reduction of stress-induced overconsumption. Practical methods to integrate de-stressing techniques into daily lives are emphasized. Homework includes strategies to practice stress reduction activities, along with long-term measures for stress reduction.

• Week 6: The sixth week instructs participants on the necessity of daily activity as a fitness strategy. Emphasis is placed on everyday movements rather than exercises one must perform within a gym environment. Specific encouragement is given to the performance of low weight, high repetition muscle toning activities. Homework includes the performance of muscle toning exercises daily, as specified by a written plan created by the participant.

• Week 7: The seventh week instructs participants on the proper selection of object goals and process goals in the identification of targeted goal planning. Behavioral chaining is discussed in the context of individuals coaching themselves. Homework includes the participants identifying and completing their own goals statements, along with the identification of specific personal behavioral chains that lead to poor eating choices and actions.

• Week 8: The eighth week is highly personalized

Exhibit 2: A1c Values

A1c Values
Measured from Program Onset (T=0)
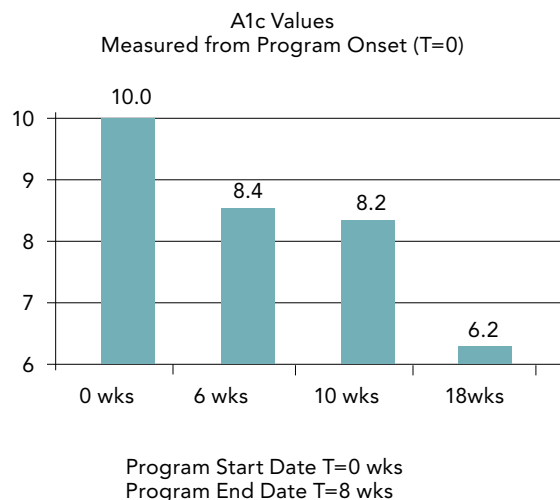
Glycosylated hemoglobin levels (HbA1c) were acquired by the subject's endocrinologist at program initiation, after 6 weeks, 10 weeks, and 18 months (all units in mg/dl).

Program Start Date T=0 wks
Program End Date T=8 wks

to each individual. The atmosphere diverges from the typical didactic format, to facilitate a support group environment focused on troubleshooting specific situations.

• Program follow-up: Following Week 8, participants receive interactive feedback with the registered dieticians in two formats: over the telephone or online. The telephone support is scheduled in coordination with participants' schedules, and consists of weekly 30-minute calls. The online support consists of email communications from participants asking information from the registered dietician, and receiving specific answers.

Individual Case Study
These data were obtained from a 33-year-old female (MF, weight 235, height 5'7", type 1 diabetes) with severely uncontrolled hyperglycemia (see Exhibit 1), who participated in the Mediterranean Wellness curriculum as a component of a corporate wellness initiative at ALCOA, Inc. in Pittsburgh, PA.

Data Acquisition: MF was instructed to collect and record the following data before, during, and after the curriculum:
• Blood glucose level (five times/day), beginning 40 days prior to curriculum onset
• Glucose readings were provided electronically through an implanted glucose monitor
• Detailed food record one week prior, and one week following the curriculum, to be recorded following each meal
• Medical bills for the six months before and after the curriculum

Results:
The prior graph (Exhibit 1) represents the timeline of glycemic changes before, during, and following the Mediterranean Wellness curriculum. The vertical line represents the onset of the curriculum. The patient's glucose record documents a substantial and rapid reduction in mean glucose from 309.94 to 98.32 mg/dl by Week 8 of the program, along with a similar decrease in the glucose excursions from (+/-)107.8 to (+/-)29 mg/dl. To date, these results have been sustained (over four years, post-program).

The standard deviation of the pre-program mean = 120.17

The standard deviation of the post-program mean = 32.42

Differences between means (pre-program vs post-program) were assessed using a two-tailed T-test with two samples of unequal variance ($p < 3.7 \star 10^{-7,6}$).
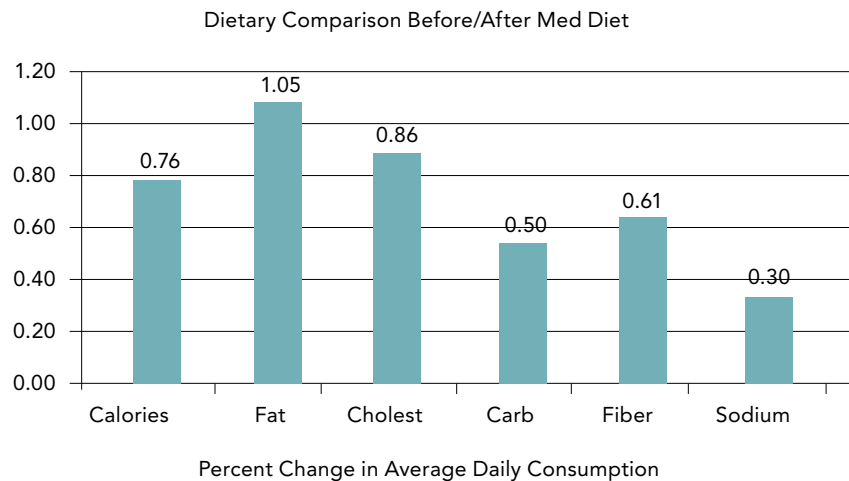
Dietary Food Record:
MF provided a detailed food record for one full week prior to the start of the program, and one full week following the completion of the program. The food record included the kind and amount of food eaten at each meal, and at each snack. Each record was analyzed for calories, fat, total cholesterol, carbohydrates, fiber, and sodium. Each of these elements was then compared to assess the percent change in consumption following the curriculum (Exhibit 3).

Weight changes:
MF experienced a gradual weight reduction during the curriculum and following its completion. After

Exhibit 3: Nutrient Analysis of Food Record

Dietary Comparison Before/After Med Diet

Nutrient	Percent Change
Calories	0.76
Fat	1.05
Cholest	0.86
Carb	0.50
Fiber	0.61
Sodium	0.30

Percent Change in Average Daily Consumption

six weeks, the weight had fallen by 10 pounds and by 13 pounds at 10 weeks. Activity levels were not assessed.

Nutrient Analysis of Food Record

The nutrient analysis in Exhibit 3 demonstrates the percent change in average daily consumption of nutrients, following the completion of the curriculum.

MF consumed 24 percent fewer calories overall, with a slightly higher overall fat content, and reductions in cholesterol, carbohydrates, and fiber. The largest change was seen in the sodium content, which was reduced by 70 percent.

Interestingly, despite the reduction in calories, MFs tendency to require a mid-morning and mid-afternoon snack abated, and she adopted a three-meal per day eating pattern.

Health Care Utilization and Cost Savings:

MF provided detailed hospitalization and medical expenses that had been incurred before and after the curriculum.

Prior to the Program

MF had been hospitalized for diabetic ketoacidosis (DKA) four times in the twelve months prior to the curriculum. The uncontrolled nature of the condition required monthly endocrinologist visits with extensive testing. Insulin usage typically reached four vials per month.

Following the Program

Insulin use was reduced by half. The requirement to visit the endocrinologist was reduced from twelve to two times per year. MF has not required hospitaliza-

tion since program onset.

Given these changes in health care utilization, the net cost savings during the first year after program completion totaled $51,360.
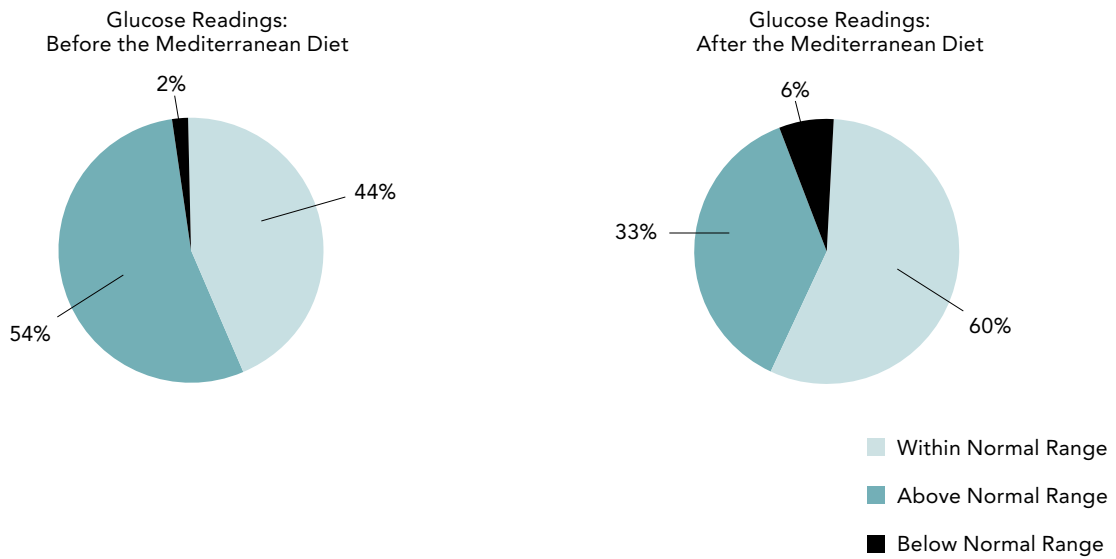
Follow-Up Study:

Patient Selection: Subjects (n=8, diabetic, type 1) were recruited from the patient pool of the diabetes clinic at the Diabetes Research Institute (DRI) at the University of Miami, under the supervision of Dr. Luigi Meneghini.

Remote Delivery Model: All subjects participated in the Mediterranean Wellness curriculum through a remote delivery model according to the following protocol. Subjects met weekly at a specified common area to receive web-based information and coaching. These weekly seminars were conducted by Mediterranean Wellness via webcast delivery and moderated by the patient education team at the DRI. In addition to the live sessions, participants could also review the weekly lectures, on demand, through a recorded version of the weekly session on the website platform.

Subjects were provided with physical and electronic versions of the participant manual to assist in the implementation of the Mediterranean dietary approach.

Data Acquisition: All participants were fitted with a continuous glucose monitor for three days before, and three days after the intervention. Glucose levels were recorded in an analog fashion, and analyzed according to the amount of time the readings were "Above Normal Range" (>180 mg/dl), "Below Normal Range" (<70 mg/dl), or "Within Normal Range" (70 – 180 mg/dl).

Exhibit 4: Glycemic Changes Resulting From Remote Delivery Model

Glucose Readings:
Before the Mediterranean Diet

Glucose Readings:
After the Mediterranean Diet

2%
44%
54%

6%
33%
60%

☐ Within Normal Range
☐ Above Normal Range
■ Below Normal Range

Because the continuous glucose monitor was used only as an assessment tool prior to, and following, the program, information from the monitor was not used to adjust insulin utilization by the patients during the intervention itself.

Results:
In Exhibit 4, the data show the average time the subjects' glucose values were:
- within normal range
  - The average time these patients spent with glycemic levels Within Normal Range significantly increased, from 44 percent to 60 percent ($p<0.02$).
- above normal range
  - The average time these patients spent with glucose levels Above Normal Range significantly decreased, from 54 percent to 33 percent ($p< 0.03$).
- below normal range
  - The average time these patients spent with glucose levels Below Normal Range increased, although not significantly ($p<0.08$).

Weight changes:
Participants experienced only slight weight reduction during the curriculum. Prior to the program, the mean weight of participants was 195.4 (range: 154 to 248 pounds). After nine weeks, mean weight was 189.0 (range: 150 to 233 pounds).

Mean individual weight loss was 6.4 pounds (range: 2 pounds gained to 15 pounds lost). Activity levels were not assessed.

Limitations:
- Small Sample Size: These data show stark short-term and long-term improvements in glycemic control within a single individual case study, and within a small group of type-1 diabetics. While compelling, the generalization of these results cannot be inferred until the study is replicated within a broader population.
- Diabetic Type and Glycemic Control: These results were found with the type 1 diabetic condition. Although the issue of disordered glycemic control is common to both type 1 and type 2 diabetics, the etiology of these conditions are not similar. Thus, it is not a foregone conclusion that this lifestyle approach will produce similar effects on type 2 diabetics. However, these data do suggest that a similar investigation of this approach on the type 2 condition is warranted.

Discussion:
Uncontrolled blood sugar can produce devastating complications. Its prevalence is increasing in all segments of the population and driving increased insurance spending. The data presented here suggest that the control and management of hyperglycemia can be achieved through a lifestyle approach cen-

tered on food selection, based on Mediterranean dietary principles, in combination with behavioral control over the quantity of food eaten. This overall lifestyle approach was associated with the immediate and sustained management of hyperglycemia in these diabetic participants and patients.

The importance of such a lifestyle approach to glycemic control is supported by the long-lasting improvements seen in MF, who experienced a large drop in A1c levels (from 10.0 to 6.2) in the weeks after the diet had already been completed. This subject, once trained in the new eating behaviors, also applied them for her family. After they were learned, these lifestyle behaviors were expressed unconsciously, as habits of healthy eating. Thus, even though the curriculum itself had been completed, the effect of the behavioral approach was sustained in MF. This potential for long-term benefits[9] represents the power and promise of lifestyle behavioral strategies.

As a managed care strategy, even modest reductions in the prevalence of diseases associated with lifestyle-related risk factors, such as hyperglycemia, can produce dramatic cost savings, particularly for private plans.[4] In addition, the remote delivery model presented here offers the possibility to extend access to patients across a wide geography, while maintaining the effectiveness of the intervention.[8] In this way, utilization of existing technology (through web-casting interventions) may help reduce the cost of care without compromising the effectiveness.

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