

Research Article





# Successful symbiotic partnership between primary care physicians and a disease management program in the treatment of prediabetes

#### **Abstract**

Aim: As physicians, we have a mandate from our government to improve quality of care while reducing the cost of care. Primary care physicians have difficulty treating chronic conditions such as obesity, prediabetes, and diabetes due to time constraints and scope of practice. The Diet of Hope Institute is a disease management program specializing in the treatment of chronic diseases. The Center for Disease Control and Prevention (CDC) suggests that primary care providers should refer their patients to a specialized program for chronic diseases if they are unable to provide the appropriate care.

Methods: Of 2,000 consecutive patients referred to our program, 833 patients were found to be prediabetic with a HbA1c of 5.7 to 6.4. Patients were seen weekly for a minimum of six weeks and followed a low carbohydrate, normal protein diet, receiving intense counseling, and suggestion of lifestyle changes. We report our data collected for these patients during the six week period.

Results: Average weight loss of these 833 patients was 17.3 pounds or 7.6% of body weight. Of 585 patients with an initial HbA1c of 5.7% to 5.9%, 427 patients (73.0%) normalized their HbA1c. Of 248 patients with an initial HbA1c of 6.0% to 6.4%, 87 patients (35.1%) normalized their HbA1c.

Conclusion: Prediabetes can frequently be corrected with appropriate nutrition, intense counseling, and lifestyle changes. The disease management program sponsored by the Diet of Hope aides the primary care physician in improving quality of care while reducing the cost of care.

Keywords: prediabetes, diabetes, hypertension, low carbohydrate diet, lifestyle changes

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## Introduction

Based on data from the American Diabetes Association, 79million adult Americans have prediabetes. The accepted diagnostic criteria for prediabetes are elevated fasting blood sugars of 100mg/dl to 125mg/dl, an elevated plasma glucose level (after an oral glucose tolerance test) of 140-199mg/dl, or a glycated hemoglobin (HbA1c) value of 5.7%to 6.4%. The incidence of prediabetes increases with age. Patients age 20 and older have a 35% incidence of prediabetes compared to 50% at age 65 and older. According to the Center for Disease Control and Prevention (2012), nine out of ten people do not know they have prediabetes. Without lifestyle change, the majority of people with prediabetes will be diagnosed with diabetes within the next ten years (National Institute of Diabetes and Digestive and Kidney Disease). A systematic review of prospective studies in prediabetic patients found that the five year risk of developing diabetes in patients with an HbA1c of 6.0% or higher was 25% to 50%. The relative risk of diabetes was 20times higher if HbA1c was greater than or equal to 6.0% compared to an HbA1c of 5.5%. 1,2 Additionally, studies suggest that long-term damage to end-organs associated with diabetes may start in patients diagnosed with prediabetes.<sup>2,3</sup> National annual medical costs associated with prediabetes in 2007 exceeded \$25 billion, or an additional \$443 for each adult with prediabetes. Prediabetes is often associated with obesity, hypertension, and metabolic syndrome.

#### Methods and materials

## **Population**

Over an eighteen month period, 2,000 patients were referred to

our disease management and prevention program, the Diet of Hope. Of these 2000 patients, 833 patients were prediabetic. We report our results of these 833 prediabetic patients treated with a lifestyle intervention program. Patients were primarily referred for the treatment of obesity and diabetes. Only 40% of patients were aware of their prediabetic condition. The Diet of Hope supports comprehensive dietary and behavioral change and provides low carbohydrate food with normal protein and plentiful non-starchy vegetables. Patients are seen on a weekly basis for a minimum of six weeks and our data are based upon completion of this six week interval. The diet has also been very successful in the treatment of patients with arteriosclerotic heart disease, chronic renal failure and diabetes and obesity.<sup>5,6</sup> Of 2,000 consecutive patients referred to the Diet of Hope program, 833 patients were found to be prediabetic based on an initial HbA1c result of 5.7 to 6.4%. Of those 833 patients, 692 patients were obese (83.1%) and the remaining 141 patients were overweight (16.9%). The average age was 58.7 years. The majority of patients were women (73.5%). Additional major medical problems were hypertension (55.3%) and metabolic syndrome (55.6%) (Table 1).

Table I Demographic Characteristics of the Study Population

|                    | # of PTs | % of PTs            |
|--------------------|----------|---------------------|
| Number of Patients | 833      | 26.5% (M)/73.5% (F) |
| Obese              | 692      | 83.10%              |
| Hypertensive       | 461      | 55.30%              |
| Metabolic Syndrome | 463      | 55.60%              |
|                    |          |                     |





Table continued...

|                | # of PTs | % of PTs     |
|----------------|----------|--------------|
|                | Avg.     | Range        |
| Age of Patient | 58.7     | 14 to 89 y/o |

F, female; M, male; y/o, years old

#### **Measures**

Most patients with prediabetes are insulin resistant and generally have elevated insulin levels. Weight-loss and exercise improves insulin resistance and lowers insulin levels. The culprit for the epidemic of obesity and diabetes is excessive consumption of refined and simple carbohydrates. Weight loss is best achieved by reducing carbohydrate consumption. The Diet of Hope program initially eliminates all the carbohydrates recommended by the 1992 Food Pyramid (bread, pasta, cereal, rice, and sugar). Eating carbohydrates from non-starchy vegetables is encouraged. Protein intake is calculated at 0.5gm per pound body weight. Omega 3, omega 6, and omega 9 are the preferred fats for consumption and portion control is encouraged. Every patient receives a daily menu guide; this is crucial because most patients cannot determine what to eat if refined and simple carbohydrates are eliminated. Addiction to carbohydrates is common and addiction is addressed on every visit. Our diet is gluten and lactose free. All patients on diuretics stopped diuretics at the start of the program. A significant diuresis occurs in the first few days after starting the program, eliminating the need for diuretics. In our study, we used HbA1c testing to establish the initial diagnosis of prediabetes. In order to determine HbA1c normalization rate, we tested each patient again after six weeks on the program.

## Statistical analysis

The patients' average age was determined and they were sorted

Table 2 Change in Vitals and Labs at Six Weeks on Program

| Statistic   | Weight (lbs) | вмі         | Waist<br>(inches) | Systolic BP<br>(mmHG) | Diastolic BP<br>(mmHG) |       |
|-------------|--------------|-------------|-------------------|-----------------------|------------------------|-------|
| Avg. Change | 17.3         | 2.8         | 2.83              | 5.7                   | 3.7                    |       |
| % Change    | 7.60%        | 7.60%       | 6.30%             | 4.50%                 | 4.80%                  |       |
| Statistic   | CHOL (mg/dL) | HDL (mg/dL) | LDL (mg/dL)       | TRG (mg/dL)           | CHOL/HDL               | HbAlc |
| Avg. Change | 17           | 2.6         | 7                 | 36.7                  | 0.2                    | 0.4   |
| % Change    | 8.90%        | 5.10%       | 6.60%             | 21.00%                | 4.80%                  | 6.80% |

BMI, body mass index; BP, blood pressure; CHOL, total cholesterol; HbA1c, glycated hemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein; TRG, triglycerides

 Table 3 Descriptive Statistics Concerning Medication Changes

|                           | # of PTs | % of PTs |
|---------------------------|----------|----------|
| Off Hypertension Meds     | 152      | 33.00%   |
| Reduced Hypertension Meds | 165      | 35.80%   |

Meds, medications; PTs, patients

Table 4 Normalized HBA1c Results at Six Weeks Based on Initial Value

| Start HbAIc | # PTs Normalized | % PTs Normalized |  |
|-------------|------------------|------------------|--|
| 5.7 - 6.4%  | 514              | 61.70%           |  |
| 5.7 - 5.9%  | 427              | 73.00%           |  |
| 6.0 - 6.4%  | 87               | 35.10%           |  |

HbA1c, glycated hemoglobin; PTs, patients

by each diagnosed medical condition to determine the percentage of patients existing in each category. The difference between starting values measured at induction into the program and the value obtained after six weeks on the program, as well as average change and percent change, for each relevant category were calculated. By tracking medication changes throughout the course of the program, statistics concerning the frequency of reducing and discontinuing various blood pressure medications were calculated. In our study, we used HbA1c testing to establish the initial diagnosis of prediabetes. In order to determine HbA1c normalization rate, we tested each patient again after six weeks on the program. If the HbA1c measurement after six weeks on the program was 5.6% or lower, it was counted as a successful normalization.

#### Results and discussion

## **Results**

Average weight loss after six weeks was 17.3 pounds or 7.6% of body weight. Average waist circumference was reduced by 2.8inches. Triglycerides lowered substantially in all patients. Average reduction was 36.7mg/dl (21.0%). Total cholesterol decreased by 17mg/dl (8.9%) and HDL cholesterol increased by 2.6mg/dl (5.1%) (Table 2) Of 461 patients with hypertension, 152 patients (33%) were able to stop blood pressure medications and 165 patients (35.8%) reduced blood pressure medications (Table 3). Despite this reduction of medications, average systolic blood pressure decreased 5.7mmHg and diastolic blood pressure decreased 3.7mmHg (Table 2). Average HbA1c reduction of all patients was 0.4% (Table 2). Of 585 patients with a starting HbA1c from 5.7% to 5.9%, a total of 427 patients (73.0%) normalized their HbA1c. Of 248 patients with an HbA1c from 6.0% to 6.4%, a total of 87 patients (35.1%) normalized their HbA1c (Table 4).

# **Discussion**

Guidelines from the American Diabetes Association (ADA) suggest that patients who are diagnosed with prediabetes be referred to an effective ongoing support program, with a weight loss goal of 5% to 10% of their current body weight, as well as a call for an increase in physical activity of at least 150minutes per week. A consensus statement from the American Association of Clinical Endocrinologists (AACE/ACE) recommends that lipid and blood pressure goals should be the same for patients with prediabetes as those with diabetes. Essentially, the differentiating numbers used to separate prediabetes from diabetes are useless in terms of treatment goals. Studies suggest that long term damage to end-organs associated with diabetes start in patients diagnosed with prediabetes.<sup>2,3</sup> To treat prediabetes, we must first establish the diagnoses. According to the Center for Disease Control and Prevention, nine out of ten people

do not know they have prediabetes. 60% of the prediabetic patients referred to our program were unaware of the diagnosis. Obesity increases the risk of prediabetes and cardiovascular disease.<sup>6</sup> All obese people should be screened for prediabetes.

We have reliable data from academic centers that have shown that lifestyle intervention can be very effective in the treatment of prediabetes.7 A meta-analysis study found that seven out of nine studies in prediabetic patients showed a diminished risk for progression to diabetes when treated with lifestyle intervention. The benefits of this treatment persisted for up to ten years. A 2012 study reported that reversal to normal glucose levels, even transiently, was associated with a 56% reduced risk of future development of diabetes.8-10 The prediabetic patients in our study lost an average of 17.3 pounds or 7.6% of body weight, well within the guidelines of the American Diabetic Association. Their waist shrank an average of 2.83 inches, an indication that visceral fat was lost. 55.3% of the patients had been treated for hypertension. 68.8% of these patients were able to either stop or reduce their hypertensive medications. Of the 833 patients in our study, 585 patients had an HbA1c of 5.7% to 5.9%. Of those 585 patients, 427 patients (73.0%) normalized their HbA1c after six weeks on our program. Of 248 patients with an HbA1c from 6.0% to 6.4%, 87(35.1%) normalized their HbA1c. A systematic review of prospective studies showed a direct relationship between HbA1c levels and subsequent diabetes development risk.1 The five year risk of developing diabetes in prediabetic patients with an HbA1c of 6.0% or higher was 25% to 50%. The five year risk of developing diabetes in prediabetic patients with an HbA1c below 6.0% was only 9% to 25%. The Diet of Hope has quickly gained support from most physicians in our community. Over 500 local physicians refer patients and fifty-two physicians were patients in the program. The program is medically supervised and patients are very successful. Medicare and most insurance programs accept the program which is extremely important for economically disadvantaged patients. We frequently correspond with the referring physicians and never provide primary care. Most patients are successful during the first six weeks of the program, but obtaining long term success requires periodical follow up for months or years, especially for very obese patients or patients with an extensive medical history. The program is teachable and portable and could be used by other physician groups.

#### Limitations

The HbA1c results reported in our study were conservative. In reality, the average decrease in HbA1c values was probably even more significant. We measured the HbA1c level at the start of our program and six weeks later. On average, red blood cells are replaced every twelve weeks. Some red cells that were exposed to high glucose levels prior to patients starting the program were inevitably still present during the six week re-evaluation tests and, consequently, would have contributed to the general elevation of HbA1c values.

#### Conclusion

79million people are prediabetic, most are not aware of their disease. Screening of all obese patients for possible diabetes or prediabetes should be implemented. Once patients are aware of the diagnosis they are often willing to consider a change in lifestyle. Simply suggesting a patient go on a diet, exercise, and lose weight does not produce significant results; patients need a support program. The program should be affordable and effective and the referring physician should remain in charge of the patient's primary care. Change in lifestyle frequently leads to improvement of multiple medical problems, a decreased need for medications without any sideeffect, and cost savings for the patient and medical industry. The Diet of Hope produces major positive lifestyle changes. Improving quality of care while reducing cost of care is the mandate handed down from our government organizations. The disease management program sponsored by the Diet of Hope aides the primary care physician in achieving these goals.

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None.

#### **Conflict of interest**

Author declares that there is no conflict of interest.

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