

Type 2 Diabetic Patients on Insulin Can Reduce or Eliminate Insulin with Lifestyle Change and Carbohydrate Restriction

Dietmar Gann^{1*} and Elizabeth Gann²

¹Director of the Diet of Hope Institute

²Co-director of the Diet of Hope Institute

Submission: September 9, 2015; Published: September 24, 2015

*Corresponding author: Dietmar Gann, Diet of Hope Institute, 50 E. Croydon Park Rd, Tucson, Arizona, USA, Tel: (520) 696-3438; Fax: (520) 888-2347; Email: gannde@aol.com

Abstract

Objective: Type 2 diabetes and obesity have become an epidemic. The aim of this study was to determine the response of type 2 diabetic patients on insulin through the use of dietary education, intense behavioral treatment, and lifestyle changes.

Methods: Sixty-seven type 2 diabetics on insulin were followed in our disease management program, The Diet of Hope, for one year.

Results: Twenty-six patients (40%) discontinued long-acting insulin. Thirty-two patients (49.2%) reduced long-acting insulin. Of twenty-five patients on additional short-acting insulin, twenty-two patients stopped those medications. Despite these reductions, HbA1c (glycated hemoglobin) lowered from 8.3% to 7.2%. The average combined daily insulin dosage for each patient (long-acting and short-acting) was 107.4 units at induction into the program and decreased to 33.2 units after one year. Average weight loss was 25.7 pounds.

The cohort of sixty-seven patients followed for one year reduced their combined daily insulin dosage by a total of 4,971.4 units (1,789,704 units per year). Average cost of one vial of insulin (1000 units) is approximately \$250. Cost savings in one year for these sixty-seven patients by reducing or discontinuing insulin was approximately \$447,426.

Conclusion: Type 2 diabetic patients on insulin can reduce or discontinue their insulin dosage through carbohydrate restriction and lifestyle change.

Keywords: Diabetes; Insulin; Diet; Lifestyle change; Cost

Abbreviations: HbA1c: Glycated Hemoglobin; LDL: Low-Density Lipoprotein; PTs: Patients; USDA: United States Department of Agriculture; RDA: Recommended minimum Daily Allowance;

Introduction

Data from the American Diabetes Association showed that 29.1 million Americans were diabetic in 2012; 8.1 million of those Americans were unaware of this diagnosis. 86 million Americans were pre-diabetic out of a population of 315 million. Seniors, age 65 and older, had a 25.9% incidence of diabetes. Estimated cost of care for diabetics in 2012 was 245 billion dollars; the defense budget in 2012 was 558 billion dollars [1].

Our food environment has dramatically changed over the last hundred years. Consumption of sugar and simple carbohydrates has massively increased, causing a substantial rise in the incidence of obesity and diabetes [2]. Reducing or eliminating simple

carbohydrates and sugar in the treatment of diabetic patients should be the obvious goal [3]. Diabetes cannot be prevented or cured with medications. Currently, 248,000 diabetic patients are on dialysis after receiving the best medication treatment available and 60% of lower limb amputations are related to diabetes (National Kidney Foundation 2014).

Low carbohydrate diets are frequently considered to be high protein diets. Dr. Atkins suggested there is no need to restrict protein and fat as long as we restrict carbohydrates. The Diet of Hope program provides a normal amount of protein. We calculate the protein intake for patients at 0.5 grams per pound of body weight, slightly above the minimum requirement of 0.36 grams per pound of body weight. We recently published the results of

thirty-four patients with stage three and four chronic kidney disease who were on the program for more than six months. All thirty-four patients improved their glomerular filtration rate [4].

The Accord study investigated 10,000 diabetic patients and showed that manipulating blood sugar levels towards normal using medications, such as sulfonylureas and insulin, increased the death rate. It was not clear if the risk was related to the medications or to intermittent hypoglycemic episodes [5]. A recent study from the VA hospitals investigated elderly diabetic patients on Metformin who poorly controlled their blood sugar levels. The patients were prescribed insulin in addition to Metformin. The mortality increased in the insulin treated group compared to the control group [6]. The new recommendation for diabetics on insulin is to aim at an HbA1c of 7.0% or less. If the patient has severe hypoglycemic episodes the recommendation is to aim at an HbA1c of 8.0% or less [7]. The diabetic patient remains at substantial risk for all diabetic complications as long as the HbA1c remains above 6.4%. Diabetes can neither be cured nor fully controlled using insulin and sulfonylureas.

The American Diabetic Association supported the food pyramid in 1992, believing it would lower the risk of heart disease in diabetic patients. Diabetics were supposed to eat six to eleven servings of bread, pasta, cereal, and rice. A diabetic patient is thought to have the same risk of a heart attack as a patient who has already had a heart attack. The official guidelines are that all patients age 40 to 75 should be treated with statins. Younger patients should also take statins if their LDL cholesterol is above 100mg/dl. Additionally, statins may be recommended for younger patients if they have hypertension, smoke, or are obese [8]. Recent long term studies regarding patients on statins suggest statins increase the risk of diabetes up to 9% over a six year period [9-11]. Based on these new findings, revision of these guidelines seems reasonable.

Multiple new and very expensive medications have recently become available. No long term data exists on their safety and effectiveness. The newest group of medications blocks the reabsorption of glucose in the kidneys, eliminating glucose through the urine. It would make more sense not to eat the glucose at all.

The American Diabetes Association suggests that the recommended minimum daily allowance (RDA) for carbohydrates should be 130 grams. Studies have shown that our brain can utilize 130 grams of glucose a day. These results are correct if the brain is provided with glucose as its sole energy source. However, the energy for our brain can also come from ketone bodies such as beta-hydroxy-butyric acid. Ketone bodies are formed if carbohydrate consumption on average stays below 50 grams per day. Generating these ketone bodies through a low carbohydrate diet has many benefits such as control of seizures in epileptic children [12]. Our liver is able to produce additional glucose from protein if needed. Eskimos did well on a zero carbohydrate diet as shown by anthropologist, Vilhjalmur Stefansson [13].

The mission of the United States Department of Agriculture (USDA) is to promote agriculture. A slice of pizza is considered to be a vegetable because it contains two tablespoons of tomato

paste. Congress approved this categorization because school lunches need to have at least two to three servings of vegetables. Clearly, this kind of action is only contributing to the epidemic of diabetes and obesity.

Considering there are more than 20,000 dietary books listed on Amazon promoting vastly differing nutritional ideas, it is extremely difficult to identify which advice is correct. The Diet of Hope program provides the basics of good nutrition [14]. Our body needs protein, enough but not too much. Our body needs good fats (omega 3 and omega 6), as well as vitamins, minerals, and phytonutrients. Carbohydrates should be restricted to non-starchy vegetables and berries. The aim of this study was to determine the response of type 2 diabetic patients on insulin through the emphasis of the basics of good nutrition provided by the Diet of Hope program.

Methods

The Diet of Hope is a structured, medically supervised program that teaches nutrition and portion control, provides intense behavioral treatment, and demands accountability. Patients receive a daily menu comprised of simple, readily available food. Carbohydrates are restricted to berries and non-starchy vegetables. The program is gluten and lactose free. Protein intake is individualized and generally limited to 0.5 grams per pound of body weight. The patients are seen weekly for a minimum of six weeks. Initially calories are restricted between 1,000 and 1,500 calories per day; however, patients rarely report feeling hungry. After the initial six week portion of the program, patients experiment with a wider variety of food and are allowed more daily calories. The Diet of Hope program was initially developed for the treatment of obese patients with cardiac problems and it has carefully evolved over the last ten years [15]. Major support for our program comes from the local medical community. Patients not only improve their diabetes but frequently lose weight, lower blood pressure and improve their lipid profile. There are no drugs or supplements involved and patient satisfaction is 96%. Fifty-two physicians or nurse practitioners have been patients on the program and most insurance companies have accepted the program. We have seen more than 7,000 patients over the last five years.

Population

Starting in April of 2013 and ending in May of 2014, data were collected on 1,000 consecutive patients successfully completing the program. Ninety-three of these patients were type 2 diabetics on insulin (9.3%). We were able to obtain one year follow-up data on sixty-seven of these patients. Of these sixty-seven patients, fifty-two (77.6%) were hypertensive and forty-nine (73.1%) had abnormal cholesterol or triglyceride levels. Eighteen of the patients were taking sulfonylurea drugs and sixty (89.6%) were taking Metformin. This study analyzes the results of these sixty-seven patients after the initial six weeks and after one year. The follow-up data were obtained during routine patient visits at either our clinic, the referring physicians' clinic, or through phone interviews.

Measures

At the start of the program all regular insulin was discontinued and long-acting insulin was reduced by 30% at night. All sulfonylurea drugs were stopped. In most patients, blood sugars often dropped dramatically within 24 hours of starting the program. Most diuretics were stopped. Eliminating simple carbohydrates and staying on a sodium-restricted diet produced a spontaneous diuresis, frequently lowering blood pressure. All fibrates were also discontinued. Elevated triglycerides are most commonly related to excessive consumption of carbohydrates. Insulin dosages and other medications were further adjusted as patients were monitored on a weekly basis. After six weeks, the patients were seen less frequently. Most patients were followed intermittently until they had fully incorporated the dietetic parameters of the program into their daily lives.

Results

We were able to follow sixty-seven type 2 diabetic patients on insulin for at least one year. Their average age was 62.2 years. Of the sixty-seven patients, fifty-nine were patients with obesity and eight were diagnosed as being overweight. Fifty-two patients (77.6%) were hypertensive and forty-nine (73.1%) had abnormal cholesterol or triglyceride levels (Table 1).

The first six weeks

Out of sixty-seven patients, two were on insulin pumps and reduced their dosages by half. Out of the remaining sixty-five patients, twenty-four (36.9%) stopped long-acting insulin after six weeks on the program; another forty patients reduced long-acting insulin (61.5%). Twenty-five of the sixty-four patients who stopped or reduced long-acting insulin were also on short-acting insulin and all of those patients were able to stop those

Table 1: Demographic Characteristics of the Study Population.

	# of PTs	% of PTs
Number of Patients	67	47.8% (M) 52.2% (F)
Hypertensive	52	77.6%
Hypercholesterolemia	49	73.1%
Obese	59	88.1%
	Avg.	Range
Age of Patient	62.2 y/o	39 to 85 y/o

F: Female; M: Male; y/o: years old

Table 2: Change in Insulin Medications at Six Weeks and One Year on the Program.

Insulin Medication Changes	At Week 6 (# PTs)	At Week 6 (% PTs)	At One Year (# PTs)	At One Year (% PTs)
Off Long-Acting	24 of 65	36.9%	26 of 65	40.0%
Reduced Long-Acting	40 of 65	61.5%	32 of 65	49.2%
Off Short-Acting	25 of 25	100%	22 of 25	88.0%
Reduced Insulin Pump	2 of 2	100%	2 of 2	100%

PTs: Patients

Table 3: Change in Patient Weight and HbA1c at Six Weeks and One Year on the Program.

Statistic	Weight Loss (Start to Week 6)	Weight Loss (Week 6 to One Year)	HbA1c (Start to Week 6)	HbA1c (Week 6 to One Year)
Avg. Change	20.0 lbs	5.7 lbs	(-)1.3	(+)0.2
% Change	8.0%	2.3%	(-)18.5%	(+)2.8%

Avg: Average; HbA1c: Glycated Hemoglobin

Table 4: Average Daily Insulin Dosage per Patient during the Course of the Program.

Avg. Daily Insulin Dosage Per Patient	At Start	At Week 6	At One Year	Change (Start to One Year)
Long-Acting	55.2 units	15.2 units	19.9 units	(-)35.3 units
Short-Acting	52.2 units	9.8 units	13.3 units	(-)38.9 units
Combined	107.4 units	25.0 units	33.2 units	(-) 74.2 units

Avg: Average; (-): indicates decrease

medications. One patient increased long-acting insulin during the first six weeks but was able to reduce insulin after one year (Table 2). All eighteen patients on sulfonylurea drugs discontinued those medications.

The average HbA1c decreased from 8.3% to 7.0% despite the marked reduction of insulin and other diabetic medications. Of the fifty-two patients with hypertension, twenty-five stopped or reduced a multitude of blood pressure medications. Average weight loss was 20 pounds or 8% of body weight (Table 3).

One year later

We obtained follow-up data on the same sixty-seven patients. The dosages for the two patients on insulin pumps remained at half the original dosage. Out of the remaining sixty-five patients, twenty-six were off long-acting insulin (40.0%). Twenty-two of these patients remained off after the first six weeks; four additional patients who had reduced their long-acting insulin dosage after six weeks fully stopped after one year. Thirty-two out of the original forty patients that reduced long-acting insulin continued on that reduction after one year (49.2%). As mentioned above, four patients fully stopped; four others restarted their dosages. Twenty-two out of the original twenty-five patients who stopped taking short-acting insulin were still off those medications after one year; three patients restarted their dosages (Table 2). One patient restarted sulfonylurea drugs. The average combined daily insulin dosage for each patient (long-acting and short-acting) was 107.4 units at induction into the program and decreased to 33.2 units after one year (Table 4).

HbA1c results were obtained in thirty-six patients after one year; the average increased by 0.2%. Average additional weight loss was 5.7 pounds (Table 3).

Insulin cost analysis after one year

One vial of insulin usually contains 1,000 units. The cost

of one vial of long-acting insulin quoted by local pharmacies is \$225 for insulin glargine (Lantus) and \$289 for insulin detemir (Levemir). Short-acting insulins such as insulin as part (Novolog) and insulin lispro (Humalog) cost \$214 per vial. Additionally, by using the more convenient Flex pen option, the cost per vial goes up by \$50 to \$100. For calculation purposes, we estimated the cost of one vial of insulin to be \$250.

The average combined daily insulin dosage for each patient (long-acting and short-acting) was 107.4 units at induction into the program and decreased to 33.2 units after one year. Thus, the total reduction of the combined daily insulin dosage was 74.2 units per patient (2,226 units per month or 26,712 units per year). This equates to a daily usage of 0.074 vials of insulin per patient (2.23 vials per month or 26.7 vials per year). Estimating the cost of one vial of insulin at \$250, this equates to a daily cost of \$18.55 per patient (\$557 per month or \$6,678 per year). Thus, the cohort of sixty-seven patients saved \$447,426 on insulin alone in one year (Table 5).

Aside from the obvious benefit of saving money for the patient and society, the patients gained their health back. Total average weight loss per patient was 25.7 pounds after one year. Blood pressure continued to improve despite reduced medications. HbA1c, a significant risk factor for micro and macro vascular complications, lowered significantly. We know from our previous study that a low carbohydrate diet decreases triglyceride and low density lipoprotein levels, and raises high density lipoprotein levels [15].

Discussion

Many academic programs have had success in treating and preventing diabetes with lifestyle intervention [16,17]. Low carbohydrate diets were initially promoted for the treatment of obesity [18]. Obesity is the main precursor for diabetes, so a low carbohydrate diet should also be an effective tool for the treatment of diabetes. Overconsumption of sugar was identified as a cause for obesity and diabetes [19,20]. However, no universally accepted program to treat diabetes and obesity exists. The Diet of Hope program is effective and simple. It can easily be taught and incorporated into any medical practice interested in nutrition.

We tell our diabetic patients that they are diabetic because of what they eat. This statement is true for most patients. They realize the relationship between consumption of carbohydrates and their blood sugar. Twenty-two of the twenty-five patients taking intermittent regular insulin at the beginning of the program were able to stop short-acting insulin for the whole year. No extra insulin was needed if only carbohydrates from

non-starchy vegetables were consumed.

Carbohydrate-restricted diets can safely lower blood sugar levels in diabetic patients as long as the patient is on medical supervision and medications are adjusted as needed. Instructing a diabetic patient to consume a low fat diet with 60% of their calories comprised of carbohydrates, even if they are complex carbohydrates, is essentially promoting diabetes and obesity. Diabetics are unable to process carbohydrates safely and effectively.

We are aware that our approach to diabetes is different from the recommendation of the American Diabetic Association. However, their recent nutrition recommendations are becoming more accepting of a low carbohydrate diet for the treatment of diabetes. The American Diabetic association stated in their most recent guidelines that foods and beverages high in carbohydrates are the greatest determinant of the post meal blood glucose level [14].

Our program has been successful in over 7,000 patients; it appears to be especially effective in diabetic patients. Patients learn that the food they were eating caused and aggravated diabetes. Once they understand they can control their diabetes by changing their diet, they become highly motivated to escape the dreadful and debilitating destiny of diabetes. It is the consensus of most my colleagues that once patients start insulin medications they will be on insulin for the rest of their lives. Our results from this study disprove this belief. Some patients can even become non-diabetic (based on their HbA1c results) as long as they do not revert to their previous eating habits.

Treatment of diabetes is expensive. As previously discussed the estimated cost of diabetes care is 245 billion dollars per year. Diabetic medications, especially insulins, are continually increasing in price. The results of this study prove that the Diet of Hope program significantly alleviates the financial burden associated with diabetes care for both patients and insurance companies.

Conclusion

Type 2 diabetic patients on insulin following a low carbohydrate, normal protein diet, while under medical supervision, can substantially lower or discontinue their insulin dosage and lose significant weight for at least a one year period. They also improve their blood pressure, lipid profile, and general health. Reduction of medications creates major cost savings. In the future, medical professionals will be judged on quality and cost of care. Our program provides high quality patient care while also lowering the cost of care substantially.

Limitations

Out of a cohort of ninety-three type 2 diabetic patients on insulin, we were only able to obtain one year follow-up data for sixty-seven patients. Due to the fact that the Diet of Hope Institute does not practice primary care, obtaining follow-up data was difficult. Patients frequently change physicians or contact information. We only used verifiable data. Data could be biased because successful patients might be more likely to provide follow-up data.

Table 5: Total Cost Savings from Combined Insulin Reductions.

Population	Daily	Monthly	Yearly
Per PT	74.2 units 0.074 vials \$18.55	2,226 units 2.23 vials \$557	26,712 units 26.7 vials \$6,678
Per Cohort of 67 PTs	4,971.4 units 5.0 vials \$1,243	149,142 units 149.1 vials \$37,285	1,789,704 units 1,789.7 vials \$447,426

PTs: Patients

Acknowledgement

The authors are indebted to Ryan Holt (Research Fellow at the Diet of Hope Institute) for data acquisition and analysis.

References

1. American Diabetes Association (2015) Statistics about Diabetes.
2. Hu FB (2011) Globalisation of Diabetes. The role of diet, lifestyle, and genes. *Diabetes Care* 34(6): 1249-1257.
3. Malik VS, Popkin BM, Bray GA, Despres JP, Willet WC, et al. (2010) Sugar sweetened beverages and risk of metabolic syndrome and type 2 diabetes: a meta-analysis. *Diabetes Care* 33(11): 2477-2483.
4. Gann D, Gann E (2015) A Low Carbohydrate Diet Effective in the Treatment of Obese or Diabetic Patients with Chronic Kidney Disease. *J Diabetes Metab Disord Control* 2(2): 1-4.
5. Gerstein HC, Miller ME, Byington RP (2008) Effects of intensive glucose lowering in type 2 diabetics. *N Engl J Med* 358(24): 2545-2559.
6. Roumie CL, Greevy RA, Grijalva CG, Hung AM, Xulei L, et al. (2014) Association between intensification of metformin treatment with insulin vs sulfonylureas and cardiovascular events and all-cause mortality among patients with diabetes. *JAMA* 311(22): 2288-2296.
7. American Diabetes Association (2015) Glycemic targets. Sec.6. In *Standards of Medical Care in Diabetes-2015*. *Diabetes Care* 38(Suppl. 1): S33-S40.
8. American Diabetes Association (2015) Statin therapy and diabetes. *Diabetes Care* 38(Suppl 1): S49-S57.
9. Besseling J, Kastelein JP, Defesche JC, Hutten BA, Hovingh GK (2015) Association between familial hypercholesterolemia and prevalence of type 2 diabetes mellitus. *JAMA* 313(10): 1029-1036.
10. Sattar N, Taskinen MR (2012) Statins are diabetogenic-myth or reality? *Atheroscler Suppl* 13(1):1-10.
11. Axsom K, Berger JS, Schwartzband AZ (2013) Statins and diabetes: the good, the bad and the unknown. *Curr Atheroscler Rep* 15(2): 299.
12. Neal EG, Chaffe H, Schwartz RH, Lawson MS, Edwards M, et al. (2008) The ketogenic diet for the treatment of childhood epilepsy: a randomized trial. *The Lancet Neurol* 7(6): 500-5006.
13. Stefansson V (1936) *Adventures in Diet*. Reprint from *Harpers Monthly Magazine*. Chicago: Institute of American Meatpackers.
14. American Diabetes Association (2013) *Nutrition Recommendations and Intervention for Diabetes*. *Diabetes Care* 36(Suppl 1): S12-S32.
15. Gann D (2004) A low carbohydrate diet in overweight patients undergoing stable statin therapy raises high-density lipoprotein and lowers triglyceride levels substantially. *Clin Cardiol* 27(10): 563-564.
16. Tuomilehto J, Lindstrom J, Ericson J, Valle T, Hamalainen H, et al. (2002) Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *N Engl J Med* 344(18): 1343-1350.
17. Knowler W, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, et al. (2002) Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med* 346(6): 393-403.
18. Pennington AW (1954) Treatment of Obesity: Development of the past 150 Years. *American Journal of Digestive Diseases* 21(3): 65-69.
19. Yudkin J (1959) The Causes and Cure of Obesity. *Lancet* 274(7112): 1135-1138.
20. Lustig RH, Schmidt LA, Brindis CD (2012) Public health: The toxic Truth about Sugar. *Nature* 487(7383): 27-29.