

Case Report

Glucose Tolerance Test Clearance in Type 2 Diabetes Mellitus Patients Following a Plant Based Diet and Anti-Gravity Exercise: A Case Series

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Abstract: The following case series documents six patients consulted in the Freedom From Diabetes Research Foundation (FFDRF) in Pune, India, for the treatment of type 2 diabetes mellitus (DM). This study aims to determine the effectiveness of a specifically modified plant based diet combined with anti-gravity exercises (FFD protocol) towards the cessation of the use of oral hypoglycemic agents (OHAs) and/or external insulin to control blood glucose levels and have the ability to clear the Glucose Tolerance Test (GTT). The patients selected for the study had a minimum of 10 years diabetes. Four of them were only on OHAs and two were on external insulin and OHAs. They had followed the FFD protocol and were included in this study only after fulfilling the following parameters- latest average glycated hemoglobin (HbA1C) levels less than 6.5 and not taking any OHAs or insulin for the last 3 months. Initial and latest demographic data was collected. This included weight, waist circumference, fasting blood glucose levels and HbA1C levels. All 6 patients showed a major improvement in the HbA1C levels, loss in body weight and reduction of waist circumference. In conclusion to this case series, these patients were able to undergo and clear the GTT. This study shows that all these patients have reached an advanced stage of diabetes reversal; besides becoming free from any kind of medications, they are also able to handle a 75 gram glucose load with ease. This would have been otherwise impossible for them. Such results are an important milestone in the history of type 2 diabetes mellitus management and give immense hope to diabetics, their family members, diabetes educators, doctors and the world at large.

Keywords: Type 2 Diabetes Mellitus (DM), Freedom from Diabetes (FFD) Protocol, Oral Hypoglycemic Agents (OHA), Glucose Tolerance Test (GTT), Glycated Haemoglobin (HbA1C)

1. Introduction

Non-communicable Diseases (NCDs) are a major threat for global health responsible for 72% of deaths in 2016 [1]. Type 2 diabetes mellitus (DM) is among the four major NCDs which need immediate global attention [1]. International Diabetes Federation estimated that approximately 425 million people were diabetic in the year 2017 [1]. This number is expected to rise to 629 million by the year 2045. Recent epidemiological data states that nearly 387 million people globally are affected from DM with a prevalence rate of 8.3%

and the undiagnosed cases remains 46.3% [1]. Due to westernized lifestyles and eating habits, more of the younger population is now suffering from diabetes. There is an increase in the rate of obesity, which implies that diabetes mellitus will always remain a public health burden [2]. To prevent chronic complications of diabetes, multiple protocols have been developed to strictly control blood glucose [3]. To reduce the socioeconomic burden caused by diabetes, identifying patients with impaired glucose tolerance or impaired fasting tolerance would be beneficial as this is a pre-diabetic stage [4].

Glucose Tolerance Test (GTT) is used as the gold standard for diagnosis in diabetes and pre-diabetes [5]. To determine whether people are diabetic and insulin resistant, they are given 75 gm of sugar solution in a fasting state [5]. People are asked to check their blood glucose levels after 1 hour and 2 hour interval [5]. If the 1 hour interval blood glucose is less than 100 mg/dl and 2 hour blood glucose interval is less than 140 mg/dl, it is concluded that the person is non-diabetic and has cleared the GTT [6]. If the 1 hour interval blood glucose level is less than 180 mg/dl or the 2 hour interval blood glucose level is less than 200 mg/dl and greater than 140 mg/dl, that person is categorized as prediabetic or as said to be having an Impaired Glucose Tolerance (IGT) [6]. A person is considered to be diabetic when the 1 hour interval blood glucose level is greater than 180 mg/dl and 2 hour interval blood glucose level is greater than 200 mg/dl. This is also considered as GTT fail [6].

The study was approved by Royal Pune Independent Ethics Committee with DCGI Reg No: ECR/45/Indt/MH/2013/RR-16.

This case series demonstrates diabetic patients who have followed the Freedom From Diabetes protocol and have successfully cleared the GTT.

2. Case Presentation

This case series involved six patients. Data from CRM (Client Registration Management) of each patient was reviewed and completed in September 2018 after the GTT. The data includes printed notes from the referring physicians, pathology lab reports and medical history taken from each visit of the patients in FFDRF. On the initial consultation, all patients had been receiving various pharmacological therapies for DM, which included insulin as well as oral hypoglycemic agents (OHAs). Patients were asked to visit every 3 months thereafter. Patient characteristics are summarized in Table 1. Patient 1 is a 46 year old male diagnosed with DM for 12 years. Other significant history includes constipation, gases, sleep deprivation, tiredness, anxiety, fear, anger and sensory neuropathy. He had undergone surgery for anal abscess in 2011. Other deviations showed mild fatty liver and a small gall bladder calculus. Diabetic retinopathy was also observed.

Diabetic pharmacotherapy at the time of admission was insulin NovoMix 38 units, Glycomet 500 mg twice daily and Jardiance 25 mg once daily. Patient 2 is 52 year old male diagnosed with DM for 11 years. Other significant history included acidity, disturbed sleep, tiredness, burning sensation of feet, knee pain and h/o kidney stone. Diabetic pharmacotherapy at the time of admission was insulin Lantus 20 units' once daily, Glycomet GP1 half tablet at night daily, Glycomet 500 mg half tablet in the morning daily. Patient 3 is a 64 year old male diagnosed with DM for 13 years. Other significant history includes acidity, anger and itchy skin. His other deviations included tuberculosis which was diagnosed 12 years ago and hypertension was diagnosed 20 years ago. His diabetic pharmacotherapy at the time of admission was Glycomet GP1 twice daily, which was reduced to one tablet in the morning and half tablet at night. Patient 4 is a 65 year old female diagnosed with DM for 11 years. Other significant history includes acidity, hypertension, sensory neuropathy and hypothyroidism. Hypertension was diagnosed 10 years before diabetes. Other deviations showed itching and burning sensation on upper side of the feet. Her diabetic pharmacotherapy at the time of admission was Glyciphage 500 mg twice daily. Patient 5 is a 59 year old female diagnosed with DM for 11 years. Other significant history includes sleep deprivation, sensory neuropathy, hair loss, joint pain. Other deviations showed complaint of loose motions on starting the FFD diet. Surgeries undergone were hysterectomy in 2007 and fissures in 2010. Her diabetic pharmacotherapy at the time of admission was Diamicon 80 mg two tablets twice daily, Advog 0.3 mg twice daily, Galvus 50 mg twice daily. Patient 6 is an 80 year old male diagnosed with DM for 23 years. He had a history of acidity, high cholesterol, heart disease (de-shaped heart since 10 years), joint pain, oedema on both feet, right knee pain, skin itching. Hypertension was diagnosed 17 years ago. Other deviations included hernia 17 years ago, minor operation of urinary tract 15 years back, catheter inserted for UTI and prostrate operation was performed March 2018, hearing aid for ears. Cataract was operated in May 2018 and August 2018. His diabetic pharmacotherapy at the time of admission was Glycomet 500 mg three times a day.

Table 1. Diabetic History of Patients.

Patient	Age	Sex	Years with Type 2 Diabetes	Initial Diabetic Medication	Followed the FFDRF Protocol	Free from Medicine after following FFD Protocol	Months off OHA/Insulin before GTT	GTT Score (mg/dl)
Patient 1	46	Male	12 years	Insulin NovoMix 30/70 38 units Glycomet 500mg BD Jardiance 25mg OD	5 months	3 weeks (both)	4 months	Fasting:90 1hourinterval:118 2hourinterval:108
Patient 2	52	Male	11 years	Insulin Lantus 20 units Glycomet GP1 0.5 OD Glycomet 500mg 0.5 OD	23 months	4 weeks (Insulin) 26 weeks (OHA)	17 months	Fasting:88 1hourinterval:207 2hourinterval:134
Patient 3	64	Male	13 years	Glycomet GP1 BD	12 months	16 weeks	8 months	Fasting:78 1hourinterval:144 2hourinterval:99
Patient 4	65	Female	11 years	Glyciphage 500mg BD	12 months	2 weeks	11.5 months	Fasting:90 1hourinterval:137 2hourinterval:89

Patient	Age	Sex	Years with Type 2 Diabetes	Initial Diabetic Medication	Followed the FFDRF Protocol	Free from Medicine after following FFD Protocol	Months off OHA/Insulin before GTT	GTT Score (mg/dl)
Patient 5	59	Female	11 years	Diamicon 80mg 2BD Advog 0.3mg BD Galvus 50mg BD	43 months	4 weeks	42 months	Fasting:87 1hourinterval:121 2hourinterval:93
Patient 6	80	Male	23 years	Glycomet 500mg TDS	9 months	12 weeks	4 months	Fasting:80 1hourinterval:152 2hourinterval:106

3. Treatment

All patients were seen in the FFDRF after the initial educational seminar. This seminar was for 4-hours and called the foundation seminar program which outlined many topics including, but not limited to, the patho-physiology of diabetes, insulin resistance, education on macronutrients and the principles of dietary management of diabetes including anti-gravity exercises and safety. After completing the program, the patients were instructed to follow the FFD diet and anti gravity exercises over a period of several months. The primary intervention used in this case series was dietary intervention and medically supervised anti gravity exercises. All patients were given detailed instructions on monitoring blood glucose, insulin dosage and oral hypoglycemic agents. The dosages of insulin and OHA were reduced as per the decrease in daily sugar levels prior to every visit. Diet, exercise and pharmacological adjustments were made on a case to case basis. Over this time period, they were evaluated for glycemic control and other diabetes-related health measures. In addition, patients' weight, waist circumference was measured and HbA1C was recorded at each visit. Patients were examined on average every three months with the necessary lab reports. At each visit, patients' daily blood sugar records were reviewed and further dietary and medication modification was made if needed. Blood sugars were measured by patients at least four times daily during the period where OHA and insulin have been stopped.

4. Results

There were five outcome measures in this case series – Time taken to discontinue diabetes medication (OHAs/insulin), fasting blood glucose level (mg/dl), HbA1C level (%), patient weight (kg), patient waist circumference (cm).

Clinic based reporting was performed with patients following a whole plant based vegan diet. Results showed improvements in glycemic control and cardiovascular health. The most noteworthy outcome from this case series is the complete discontinuation of insulin and OHAs. The changes in diabetic medications of all six patients are summarized in Table 2. All six patients discontinued all diabetic medications - OHA and/or insulin entirely. There was a general reduction of glycated haemoglobin (HbA1C) levels for all patients. Patient 1, depicted in Figure 1, showed a decrease in the HbA1C drastically. His fasting blood glucose reduced from 122.0 mg/dl to 90.0 mg/dl. Further, he lost 13.4 kg weight and waist circumference reduced by 15 cm. Duration between

GTT and freedom from all medication/insulin was 4 months (Table 2). Patient 2, who followed the same FFD regimen, significantly reduced his HbA1C overall, with some fluctuations as summarized in Figure 2. Patient 2 also subjectively reported feeling 'terrific', and his daily fasting blood sugars reduced from 230.0 mg/dl to 106.0 mg/dl. Further, he had lost 6 kg weight and 8 cm of waist circumference reduction. Before attending the GTT, patient was free from medication/insulin for 17 months (Table 2). Patient 3 maintained a moderate to low HbA1C along the course with some fluctuations (Figure 3).

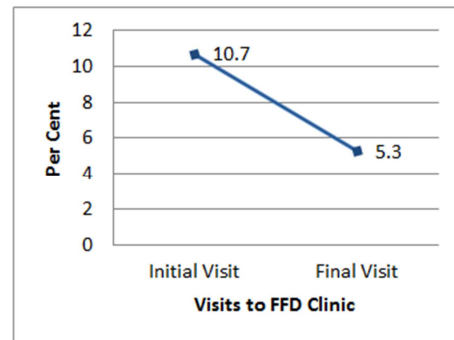


Figure 1. HbA1C values of Patient 1.

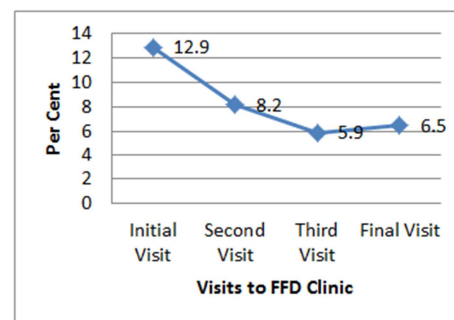


Figure 2. HbA1C values of Patient 2.

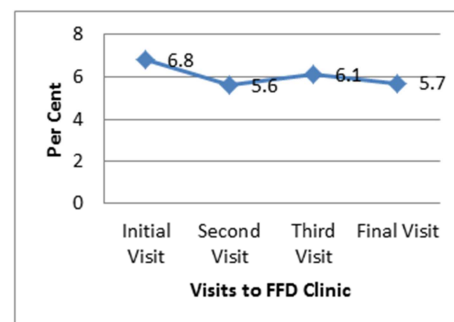


Figure 3. HbA1C values of Patient 3.

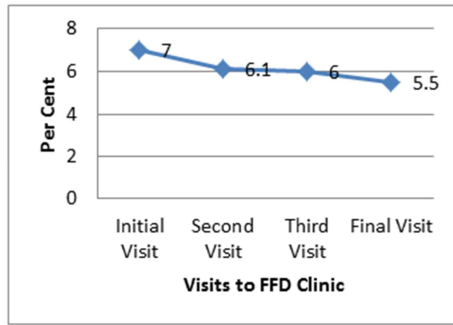


Figure 4. HbA1C values of Patient 4.

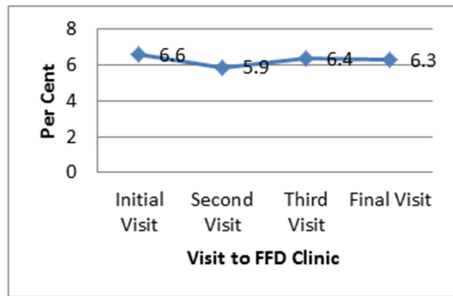


Figure 5. HbA1C values of Patient 5.

Fasting blood glucose reduction was negligible as patient reported normal fasting sugars from initial visit. He subjectively reported that after beginning the diet, he experienced higher energy levels. Further, he had lost 18.7 kg weight and 22 cm waist circumference reduction. Patient was free from medication/insulin for 8 months before attending

GTT (Table 2). Patient 4 had a gradual reduction HbA1C levels (Figure 4) with a decrease in the fasting blood glucose levels from 127.0 mg/dl to 101.0 mg/dl. She lost 2.7 kg weight and a decrease in the waist circumference by 3 cm. Patient was free from medication/insulin for around a year before attending the GTT (Table 2). Patient 5 reported with low HbA1C levels and maintained it along the course (Figure 5). Fasting blood glucose levels were low throughout the course since the initial visit. She lost 11.2 kg weight and 12 cm waist circumference. Before attending the GTT, the patient was free from medication/insulin for 42 months (Table 2). Patient 6 had moderately high HbA1C fluctuating levels which reduced after following the FFD protocol (Figure 6). Fasting blood glucose levels changed from 96.0 mg/dl to 71.2 mg/dl. He lost 18.2 kg weight and 31cm waist circumference reduction was observed. He attempted the GTT after 4 months of being free from all medication/insulin (Table 2).

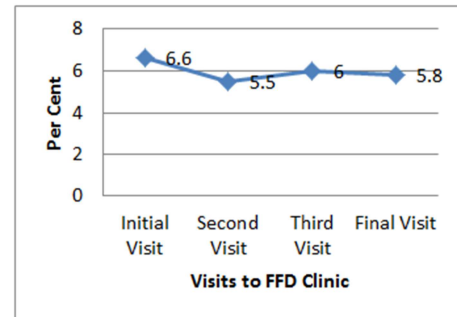


Figure 6. HbA1C values of Patient 6.

Table 2. Changes in Glycemic and Physical Parameters from Baseline to End of Follow-up.

Patient	Initial HbA1C (%)	Final HbA1C (%)	Initial Fasting BSL (mg/dl)	Final Fasting BSL (mg/dl)	Initial Weight (kg)	Final Weight (kg)	Initial Waist Circumference (cm)	Final Waist Circumference (cm)
Patient 1	10.7	5.3	122.0	90.0	73.1	59.7	98.0	83.0
Patient 2	12.9	6.5	230.0	106.0	72.0	66.0	93.0	85.0
Patient 3	6.8	5.7	88.02	80.0	89.9	71.2	114.0	92.0
Patient 4	7.0	5.5	127.0	101.0	57.7	55.0	85.0	82.0
Patient 5	6.6	6.3	86.79	85.0	66.4	55.2	98.0	86.0
Patient 6	6.6	5.8	96.0	71.2	72.9	54.7	111.0	80.0

All six patients completed the GTT and proved that 75 mg sugar was well tolerated after following the FFD protocol (Table 3). No patient stopped FFD protocol (diet and exercise) at any point, out of choice. All six patients showed improvement in their health co-morbidities like hypertension, constipation, acidity, itching or burning of the skin, disturbed sleep and oedema on the feet, gases, tiredness, anxiety and hair loss at the end of the program. In general, feedback from the patients in this program was very positive, and a number of patients commented on enjoying being actively involved in the process of managing their diabetes.

5. Discussion

The goals of caring for patients with DM are to reduce symptoms and to prevent or slow the development of complications. The main interventions for treating DM are

lifestyle modification, pharmacological and in some cases, surgical. This present case series showed that FFD regimen can significantly reverse or eliminate the need for diabetic medications including insulin. To date, however, very few studies or cases have been documented or published where after eliminating the use of insulin and/or OHA, patients have cleared GTT. After following FFD protocol, patients not only became free from medications but also cleared the GTT. They also improved in multiple other clinically significant health outcome measures, such as HbA1C, weight and waist circumference. This will reduce the risk of further complications. Risk factor reduction was even greater with loss of body weight. In our present study, all six patients experienced a weight loss of 5 kg or more. Educating patients on the benefits of the FFD protocol in the management of DM may aid in the remission of the disease and curtail the use of pharmacological interventions. A systematic review suggested

that patients with DM who have a baseline HbA1C of greater than 8% may achieve better glycemic control when given individual education rather than usual care [7]. Additionally, patients should be educated about and encouraged to follow an appropriate treatment plan tailored to them. Adherence to FFD diet should continue to be stressed throughout treatment because these lifestyle measures and modifications can have a large impact on the degree of diabetic control that patients can achieve, as seen with this case series.

Low fat vegan diet and diet based on the ADA guidelines improved the glycemic and lipid control in DM patients [8]. These improvements were greater with a low fat vegan diet. As a result, it easily exceeds the recommended limits on saturated fats [8]. Weight reducing effect of the vegan diet is responsible for a substantial portion of its effect of HbA1C. Independent of their effect on the body, weight reductions in total fat intake and in the portion of unsaturated fat, increases the insulin sensitivity [8]. Insulin resistance is related to the lipid accumulation within muscle cells (intracellular lipid) apparently due to a genetically based reduction in the mitochondrial activity identifiable many years before diabetes manifests [9]. This lipid accumulation may be responsive to the diet [9].

Individuals following plant based diets experienced reduced and improved values of glycemia, body weight and cardiovascular risk compared with those having animal product diets [10, 19]. Studies suggested that diabetes prevalence is lower in vegans and vegetarians as compared with non-vegetarians as the consumption of animal product is increased [10, 12 - 14, 17 - 20]. Plant-based diets or vegan diets are associated with weight loss along with reduction in HbA1C, improved insulin sensitivity due to consumption of reduced intake of saturated fats [10, 13, 18, 20]. A calorie restricted vegetarian diet has a greater capacity to improve the insulin sensitivity with a loss of visceral fat and improvements in plasma concentrations of adipokines and oxidative stress markers with a reduction in insulin resistance [15].

People consuming non-vegetarian diet and pesco-vegetarian diet are highly associated with the development of diabetes when compared to people consuming lacto vegetarian, lacto-ovo-vegetarian and semi-vegetarian diets [11, 12, 16, 19]. But, the protection afforded by a vegan diet was the strongest against type 2 diabetes [16]. Plant based diet contains plant polyphenol which improves glucose metabolism [17]. Several studies showed that increased vegetarian diet compliance is protected against the risk of DM along with hypertension, body weight, plasma lipid concentration and urinary albumin excretion [11, 12, 14, 16, 17, 19, 20]. Most vegetarian diets are nutritionally adequate where the dietary constituents are associated with protection against insulin sensitivity thereby reducing the risk of diabetes mellitus [11, 13, 14, 18, 20]. Vegan diets with exercise show more improved values of HbA1C, weight and BMI [13 - 15, 18, 20]. Reduced consumption of animal fat and increased consumption of low glycemic index foods help reduce the oxidative stress and chronic inflammation [11, 14, 15].

Table 3. Glucose Tolerance Test Results of each patient.

Patients	Fasting Score (mg/dl)	1 Hour Score (mg/dl)	2 Hour Score (mg/dl)
Patient 1	90	118	108
Patient 2	88	207	134
Patient 3	78	144	99
Patient 4	97	130	89
Patient 5	87	121	93
Patient 6	80	152	106

The influence of fiber in the diet reduces the glycemic load on postprandial glucose and insulin response; whole grains may reduce the risk of DM by the use of vitamin E and magnesium [11, 17]. Participants undergoing GTT with stable vegan diet showed 1.23 percent more reduction in HbA1C, weight, BMI, waist circumference, total cholesterol and LDL cholesterol [12, 13, 15, 18, 20].

Current national estimation of diabetes in India is 7% of the adult population aged between 20 to 79 years with at least 30% reduction of diabetes found on the values by using a combination of oral glucose tolerance testing [11]. 50% to 53% reduction in diabetes risk has been seen in vegan or low fat vegetarian diet in Japan and China compared to persistent use of non-vegetarian diet [16, 17].

Another study data suggested that following the FFD protocol of a specifically modified plant based diet and anti gravity exercises for a period of 10 to 14 weeks improves the glycemic control and reduces the requirement of anti-diabetic medications [21]. Results showed all 259 participants had a reduction in anthropometric measurements which included body weight, body mass index, fat percentage, visceral fat percentage, which was accompanied by lower fasting and postprandial blood glucose levels and HbA1C [21]. Due to improved glycemic status, reduction or discontinuation in dosage of OHA and insulin was observed in almost all participants [21]. A study suggested that after following the Transcendental Residential Program (TRP) of FFDRF, improved glycemic control and also observed significant weight loss [22]. Out of the 485 enrolled participants, 142 were on insulin before TRP. Among them almost 50% participants discontinued external insulin completely and 72 participants had their insulin dosage reduced by 59.07% [22]. 457 participants were on OHA before TRP, out of which almost 34% of participants discontinued OHA completely and 76% participants OHA dosages were reduced significantly [22].

A case report showed that the patient was diabetic for 15 years before visiting the FFDRF for the first time in March 2016 [23]. The patient was then advised to follow the FFD protocol (special diet and antigravity exercises) [23]. Following the FFD diet and exercise protocol immediately from the first visit, the patient was free from all diabetic medications in a record 10 days [23]. Also, the patient's medical reports showed a reversal of Grade III Fatty Liver to a Healthy Liver. The patient was asked to appear for GTT in June 2016 which was cleared just after 3 months of being free from all diabetic medication [23]. According to the data in the case report, the patient again appeared for GTT in October

2016, October 2017 and September 2018 clearing it all three times [23]. In September 2018, the GTT scores of the patient were – fasting 80 mg/dl, 1 hour interval 160 mg/dl and 2 hour interval 98 mg/dl [23].

6. Conclusion

Follow-up results of these six cases have confirmed that the FFDRF protocol helps in achieving glycemic control along with a significant reduction or complete stoppage of oral hypoglycemic medications or insulin. This also shows that FFDRF protocol if followed regularly can have a sustainable, long term effect on diabetes reversal by making type 2 diabetes mellitus patients capable of clearing the Glucose Tolerance Test (GTT) (Table 3), even if they had diabetes for more than 10 years and were prescribed with external insulin or OHAs.

Conflict of Interest

The authors declare that there is no conflict of interest.

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