

# Extent of Diabetic Nephropathy Reversal in Type 2 Diabetes Mellitus Patients by following the Freedom from Diabetes Protocol

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## Abstract

**Introduction** - The purpose of the study is to test the efficacy of Freedom From Diabetes (FFD) protocol on diabetic nephropathy patients.

**Methods** – Out of 776 participants enrolled, 302 had diabetic nephropathy. Selected participants were given a specially modified plant based diet along with lymphatic movement, anti-gravity exercises and relevant supplements to reverse the effects of nephropathy. Baseline characteristics, anthropometric measurements and biochemical parameters were measured on visit 1 and visit 2.

**Results** - After 6 months, there was a significant reduction in urinary microalbumin and serum creatinine levels which was accompanied by improvement in glycemic control. Anthropometric measurements like body weight and BMI also showed a significant improvement.

**Conclusion** - This study states that FFD protocol (specifically adapted plant-based diet along with lymphatic movement and anti-gravity exercises) with relevant supplements helps in improving diabetic nephropathy status.

**Keywords:** Plant-based diet, Exercise, Microalbuminuria, Serum Creatinine, Diabetic nephropathy.

## Introduction

Diabetic nephropathy refers to specific pathological, structural and functional changes seen in the kidneys of patients with type 2 diabetes mellitus (DM). These include the generation of advanced glycation endproducts, proteinuria, microalbuminuria, increased serum creatinine levels, elaboration of growth factors and hormonal changes<sup>1,2</sup>. DM patients consuming

acidogenic diet generate ketone bodies, leads to metabolic acidosis, which induces insulin resistance<sup>3,4</sup>. Consumption of a plant-based vegan diet reduces the risk of obesity, DM, and associated diseases<sup>5</sup>. This study discusses the efficacy of FFD Protocol on diabetic nephropathy patients.

## Materials and Methods

**Subject Selection:** It was a single centred cohort study. Out of 776 participants, 302 were having diabetic nephropathy.

**Selection criteria:** HbA1C > 6.2, Urine Microalbumin > 20 µg/ml, Serum Creatinine > 1.0 mg/dl (males) and > 0.8 mg/dl (females)

Participants with less than two visits were excluded from this study.

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FFD Protocol: The dietary & exercise intervention was carried out in 3 phases.

Phase 1 (Adjustment phase) - It lasted for 4 weeks. Strictly avoid milk and milk products and non-vegetarian foods. Replace local wheat with emmer wheat and white rice with brown/unpolished/semi-polished rice. Diet counselling was done by certified dietician through telephonic and/or personal appointment.

Diet for 1 to 3 mg/dl serum Creatinine –

Early morning: The green smoothie on empty stomach. <sup>6</sup>

Green smoothie recipe: Leach (cooking leafy vegetables in water) the locally available fresh green leafy vegetables, one low potassium fruit (apple, pear, guava and papaya) and herbs (curry or mint leaves), black pepper and low potassium salt (avoid adding lemon and low sodium salt) in 500ml water.

Breakfast: 50% raw salads (no sprouts allowed) and 50% cooked food made from pulses/lentils or grains on alternate days.

Lunch and dinner: One grain per meal with equal proportion of grain, cooked vegetables and raw salads, and only one serving of pulse/lentil preparation per meal. Include 20 to 25 ml of unrefined cooking oil (cold-pressed/ filtered) per day.

Evening: Nuts and seeds (either 2 tablespoon mix seeds like sunflower, pumpkin, watermelon, sesame, flaxseed and 2 soaked almonds or walnuts).

The diet provided approximately 65 to 70% carbohydrates, 10 to 15% proteins and 20 to 25% fat.

Dietary restriction for serum Creatinine >3 mg/dl – White smoothie on empty stomach. Avoid pulses/lentils and green leafy vegetables in their breakfast.

White smoothie recipe: Bottle gourd/white pumpkin or cucumber (one cup), one low potassium fruit (apple, pear and guava) and herbs (curry or mint leaves), black pepper and low potassium salt in 500ml water.

Dietary restriction for high Uric acid –

Completely avoid spinach black-eyed peas, red lentil, white beans and moderately consume green peas, mushrooms, cauliflower and broccoli once in 15 days.

They were prescribed medications (allopurinol in required doses) and supplements Acetyl Cysteine (150mg) and Taurine (500mg) amino acids. Monthly follow up was done with repeat test results.

Phase 1 exercise (Basic exercises) – It includes following exercises,

World Best Warm-Up (Tapping, rubbing and shaking) – Morning

Antigravity exercises (nitric oxide dump/staircase climbing) – Post 1 hour 45 minutes of breakfast, lunch and dinner.

Nitric oxide dump (alternate arm raise 20 times, squats 8 times, shoulder presses 20 times and non-jumping jacks 20 times) was for those with knee pain or not having access to staircase. The speed and duration of each activity were tailored according to individual capacity.

Phase 2 (Acceleration or aggressive phase) - Low glycemic juices were given in fixed quantities depending on their eGFR levels once a week. (Table 4) Larger quantity of smoothie, nuts or salads were allowed if feel hungry. Participants with BMI >25 did it for 8 weeks, those with 23-25 did it for 4 weeks and those with <23 were not allowed to do juice feasting. Glucose levels fluctuate/drops in this phase hence their insulin/medicine dosage was adjusted accordingly.

**Juices consumed:**

Juice	Time	Recipe
Smoothie	Morning	Refer above recipe
Red juice	Morning	800gm tomato, 250gm purple cabbage, 1 red capsicum, 1 yellow capsicum
Green Juice 1	Afternoon	500gm Ash gourd, half apple, 4 big capsicums, 1 ridge gourd, half lemon juice
Green Juice 2	Afternoon	700gm bottle gourd, 2 cups green sorrel/Chenopodium, 1 cup coriander, half lemon juice
Smoothie	Evening	Refer above recipe
White juice	Evening	500gm bottle gourd, 500gm cucumber, half lemon juice

Phase 2 Cleansing exercises - Yoga-based cleansing exercises like whole system breathing, dhauti kriyas, kapalbhati (150-300 times) along with mild strength-building exercises like lightweight training and/ or resistance band (upper body focused) exercise 15 repetitions each, 3 times a week were introduced. <sup>7</sup> Minimum of 45 min of exercise per day was advised.

Phase 3 (Inner transformation phase) – It include the stress release at an emotional level; improve awareness and healing from within. Lasts for 4 weeks and was similar to the phase 1 diet with some flexibility with respect to fruits, white rice or non-dairy sweets depending upon their glucose levels and medications. The duration of each phase vary depending upon the participant’s health, needs and adaptability.

Phase 3 exercises (Strength and Stamina building) - Participants were advised based on their liking to further specialise in strength, stamina or flexibility. A weekly proportion of 4hrs of strength, 3hrs of cardio and

2hrs of flexibility was recommended. Continue Phase 1 exercises in lesser duration. For strength and muscle gain advised to join the gym. For stamina, longer walk-jogs, cycling or swimming.

The self-reported demographic data viz. gender, age, family history, dietary compliances and exercise compliance were collected. Weight and height were measured before and after the program in the clinic. The measurements of blood glucose levels, HbA1C, insulin fasting, serum Creatinine, urine microalbumin and uric acid was performed before and after attending the program in NABL accredited labs.

Statistical Analysis - Data analysis was done using IBM – SPSS (Statistical Package for Social Sciences) version 20. Statistical Analysis was done using One-Sample T-Test and Paired T-Test.  $P < 0.05$  is considered statistically significant.

## Results

There was a comparable number of males (169) and females (133) enrolled in the study. The education of the participants varied with 85.76% being graduates and postgraduates, 7.62% had studied up to 10<sup>th</sup> and 12<sup>th</sup> grade, 3.64% were doctorates and the remaining 2.98% were diploma holder (Table 1). The average duration of DM was 13 years. Out of 302, 8 participants belonged to the age group <30 years (Mean – 25.63 years), 200 belonged to the 30 to 60 years age group (Mean – 48.84 years) and 94 belonged to the >60 years age group (Mean - 66 years). (Table 2)

There was a statistically significant decrease in the biochemical parameters like, Urine Microalbumin ( $P= 0.047^*$ ), serum creatinine (males and females) ( $P= 0.000^*$ ) and uric acid levels ( $P = 0.000^*$ ) leading to a highly significant increase in the eGFR levels (males and females) ( $P= 0.000^*$ ). Weight ( $P = 0.000^*$ ) and BMI ( $P = 0.000^*$ ) also showed significant decrease. The weight loss ranged from 0kg to 24.3kg with 50.33% lost weight between 0kg to 5kg, 31.45% losing weight between 5.1kg to 10kg and 7.28% losing weight > 10.1kg. A statistically significant decrease in fasting blood glucose levels ( $P= 0.002^*$ ) and postprandial blood glucose levels ( $P = 0.001^*$ ) was determinant of improved glycemic

control. This helped to reduce the HbA1C levels as well ( $P = 0.000^*$ ) with maximum reduction from 13.3 to 7. (Table 3)

Nephropathy status at visit 2 showed that Urine Microalbumin for participants improved such that 51.39% recorded with normal levels (< 20 µg/ml) (Table 5), 17.43% showed improvement but had levels > 20 µg/ml and 20.57% showed no improvement and/or worsened status. 10.61% were drop outs. (Fig. 1)

Serum Creatinine levels for male participants improved such that 46.93% recorded with normal levels (< 1.0 mg/dl), 27.55% showed improvement but had levels > 1.0 mg/dl and 22.46% showed no improvement and/or worsened status, while 3.06% were dropouts. Serum Creatinine levels for female participants improved such that 41.77% recorded with normal levels (< 0.8 mg/dl), 30.37% showed improvement but had levels > 0.8 mg/dl and 22.78% showed no improvement and/or worsened status, with 5.08% were drop outs. (Fig 1)

The DM status at visit 2 showed that 74.82% had a reduction in the HbA1C levels; such that 54.30% had their HbA1C levels ≤ 7 and 20.52 % had improvement but their HbA1C levels were > 7. Participants with glycemic control status worsened were 25.18%, while 8.94% were dropouts. (Fig 1).

**Table 1 – Demographic Characteristics**

Education	Frequency	Percent
10th Standard	16	5.29%
12th Standard	7	2.33%
Graduate	179	59.27%
Post Graduate	80	26.49%
PhD.	11	3.64%
Others	9	2.98%
Gender	Frequency	Percent
Males	169	55.96%
Females	133	44.03%

**Table 2 – Basal Characteristics**

Parameters	N	Mean	Std. Deviation
Diabetes Since	302	13.41	8.23
Age (Below 30)	8	25.63	4.90
Age (31 to 60)	200	48.84	7.42
Age (Above 60)	94	66.00	3.96

**Table 3 – Biochemical Characteristics at Visit 1 and Visit 2**

Parameters	Before		After		t Value	p Value
	Mean	Std. Deviation	Mean	Std. Deviation		
Urine Microalbumin	134.72	582.48	44.22	62.68	1.9985	0.047*
Serum Creatinine (Males)	1.27	0.32	1.15	0.46	4.1742	0.000*
Serum Creatinine (Females)	1.08	0.41	0.95	0.39	5.1523	0.000*
eGFR (Males)	66.54	14.99	81.14	29.85	-6.1559	0.000*
eGFR (Females)	62.54	17.09	74.4	26.57	-5.8549	0.000*
Uric Acid	5.67	1.49	5.2	1.41	4.7356	0.000*
Weight	71.71	13.3	67.18	13.01	18.7077	0.000*
BMI	26.88	4.2	25.01	4.61	11.7291	0.000*
HbA1C	8.24	1.65	6.9	1.07	15.3137	0.000*
Fasting Blood Sugar	133.04	49.84	123.28	34.76	3.1039	0.002*
Postprandial Blood Sugar	183.59	69.59	154.44	56.86	3.5541	0.001*

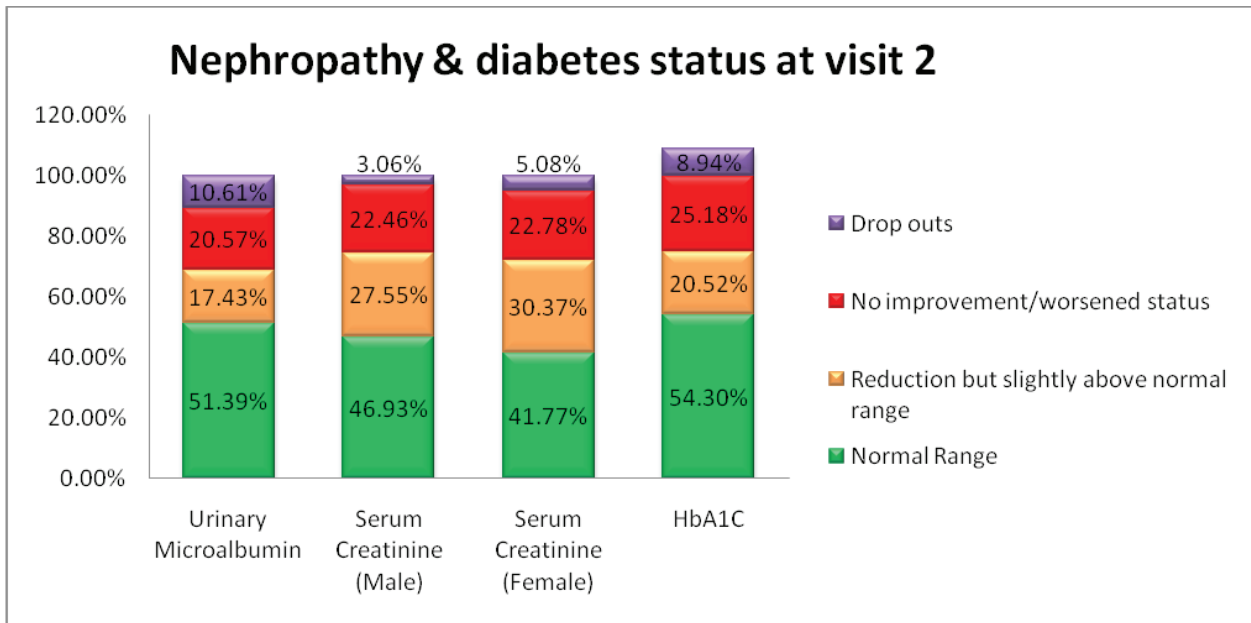
Statistically Significant – p value < 0.05

**Table no. 4 Fluid requirement on the day of juice feasting**

No.	Condition	Total fluid intake/day (ml)	Smoothie split up	Juices spilt up	Water/ green tea (ml)	Salt /day
1	Normal eGFR>90	3000-3500	2 glasses of 250ml	10 glasses of 250ml	500	5gm (normal/rock salt)
2	Mild impairment eGFR 60-90 or Any heart ailment with Ejection fraction >40% or undergone CABG or High uncontrolled BP even on medication	1500	2 glasses of 200ml	4 glasses of 200ml	300	3gm (normal salt only)
3	Moderate impairment eGFR 30-60 or Ejection fraction 25-40%	750	2 glasses of 120ml	4 glasses of 120ml	30	1 gm (normal salt only)
4	Severe impairment eGFR <30 or Ejection fraction <25%	As per nephrologists' recommendation	No smoothie	2 times bottle gourd juice of 100-125ml	As per nephrologists' recommendation	

**Table 5 – Albuminuria Classification**

Stage	Urine with marked time ( $\mu\text{g}/\text{min}$ )	24-hour urine (mg/ 24h)	Random Urine Sample	
			Albumin Concentration (mg/l)	Albumin/Creatinine Ratio(mg/g)
Normoalbuminuria	< 20	< 30	< 17	< 30
Microalbuminuria	20-199	30-299	17-173	30-299
Macroalbuminuria	$\geq 200$	$\geq 300$	$\geq 174$	$\geq 300$



**Figure 1: Nephropathy & diabetes status at visit 2 Discussion**

Diabetic nephropathy is responsible for 40–50% of all cases of end-stage renal disease.<sup>4</sup> The present study focused on a specifically adapted plant-based diet and complete muscle activation through antigravity, cleansing and strength/stamina building exercises in a phase-wise manner for improving their health. In the first phase, increased intake of cooked vegetable and a raw salad in lunch and dinner helped in reducing portion size. While in the second phase, juice feasting helps in removing all the toxins from the body and weight reduction. The juices are rich sources of phenolic compounds that are responsible for antioxidative, immunomodulatory and antimicrobial activities.<sup>9</sup> Juices made from raw vegetable retain all essential antioxidants and enzymes.<sup>10</sup> Enzymes not only aid in digestion but also help all other metabolic processes work properly.<sup>11</sup> Different colour of juices was specific for energizing, balancing and healing their corresponding colour related chakras.<sup>12,13</sup> Like red colour for root chakra (base of the spine), green colour for heart chakra (heart) and white colour for crown chakras (Head).<sup>12,13</sup> Following this diet regimen helped in improving their blood glucose levels and weight in the second phase than in the first phase. Blood glucose control and weight reduction helps in controlling preexisting chronic kidney disease and preventing a further decrease in kidney function.<sup>14,16</sup> Insulin resistance reduced by removing milk and milk products.<sup>15</sup> Consumption of milk and milk products, and

animal foods are responsible for high albumin-creatinine ratio leading to chronic kidney disease.<sup>16,17</sup> Whereas the plant-based protein diet improve kidney function.<sup>2-4,14,16</sup> Incorporation of smoothie in both phases caused an increased sensation of satiety due to high dietary fibre content, lead to weight reduction.<sup>18</sup> Smoothie is rich in fibre, phytonutrients and antioxidants help in reducing blood glucose levels, inflammation and blood cholesterol levels.<sup>6,18</sup> Nuts reduces the development of diabetes and are high in monounsaturated fatty acids, polyunsaturated fatty acids, vegetable protein, fibre, vitamins and minerals.<sup>19</sup>

Physical exercise training helps in weight reduction and improvement of insulin sensitivity, hyperlipidemia and diabetic nephropathy.<sup>3,20</sup> In diabetes, nephropathy gets aggravated by down-regulation of nitric oxide. Recently, exercise was reported to up-regulate renal eNOS and nNOS expression. Stepwise implementation of lifestyle changes with vegan diet and exercise leads to 61% reduction in diabetic nephropathy.<sup>2</sup> Incorporation of amino acids supplements like Acetyl Cysteine (150mg) and Taurine (500mg) protect kidneys from damage and reduce the risk of kidney failure.<sup>21,22</sup>

This study states that the FFD protocol helps in improving glycemic control along with serum creatinine, uric acid, urine microalbumin which helps in reversal of diabetic nephropathy.

**Informed Consent:** Obtained from all participants included in the study.

**Ethics Clearance:** Taken from M.C.E. Society with DCGI Reference No: MCES/EC/548/2019.

**Funding Source:** Self

**Conflict of Interest:** Nil

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