



# Renal Nutrition Forum

A Peer Reviewed Publication of the Renal Dietitians Dietetic Practice Group

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In This Issue

Feature Article

2

**Letter from the Editor** 

11

Nutritional Assessment of an Adult Receiving Dialysis

18

**Member Spotlight** 

23

ADA House of Delegates (HOD) Report

24

**Calendar of Events** 

25

Renal Dietitians Chair Message

26

CRN Chairperson Message

26

MAY 2011 Board Certified Specialists in Renal Nutrition (CSR)

27

RPG Executive Committee

### The Supplemented Vegan Low Protein Diet in Chronic Kidney Disease

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This article has been approved for 2.0 CPE units. The online CPEU quiz and certificate of completion can be accessed in the Members Only section of the RPG web site via the My CPEU link. This CPE offering is available to current RPG members only and the expiration date is October 31, 2012.

#### **Abstract**

A gap in patient care exists in the area of nutrition for chronic kidney disease (CKD) stages 1-4 with only 3.6% of patients seeing a renal dietitian before initiating dialysis.

Nutrition education with regard to the type and amount of protein is an important aspect of care. Research supports the benefits of protein restriction and the use of plant-based protein. Furthermore, supplementing the diet of CKD patients on low protein regimens with ketoanalogues of amino acids has been shown to help maintain nutritional status. Each intervention can be viewed independently as an effective treatment for CKD. Combining these approaches creates a supplemented vegan low

protein diet (SVLPD). This nutritional intervention improves uremic symptoms and slows progression of kidney damage without a decline in nutrition status. Improvements in nutritional parameters have been shown with SVLPD. Regular follow up and education by renal dietitians improves compliance among patients with SVLPDs. Additional research and in-depth cost benefit analysis for this approach as a best practice for CKD patient care is required.

#### Introduction

Data from the United States Renal Data Systems (USRDS) reveal increasing rates of kidney failure with an expected 2 million dialysis patients in the US alone by the year 2030 (1). Nutritional interventions to prevent kidney damage, alleviate symptoms of uremia, slow disease progression, and prevent malnutrition if damage has already taken place, should be encouraged as a best practice (2). Manipulation of the diet of CKD patients, especially with regard to the type and amount of protein, is an important aspect of care. Selected studies from 1990-2010 were reviewed regarding diets with various protein sources and levels and their effect on the prognosis of CKD. Research supports the benefits of protein restriction and use of plant based protein sources along with other restrictions such as phosphorus and potassium. While mineral monitoring and limitation is necessary for CKD patients, this paper will focus on protein and its effect on kidney preservation. Supplementing the diet with ketoanalogues of amino acids (ketoacids-KAs) has been shown to improve nutritional parameters in CKD patients (3).

- Continued on page 3.

### RPG

Renal Nutrition Forum is published quarterly (summer, fall, winter, spring) as a peerreviewed publication of the Renal Dietitians Dietetic Practice Group of the American Dietetic Association.

The views expressed in this publication are those of the author and are not necessarily those of The American Dietetic Association. Publication of an advertisement in the Forum should not be construed as endorsement by the RPG of the product or the advertiser.

Articles about successful programs, research interventions, evaluations and treatment strategies, educational materials, meeting announcements and information about educational programs are welcome and should be emailed to the editor by the next deadline.

#### **Future Deadlines:**

March 1, 2012 June 1, 2012 September 1, 2012 December 1, 2012

Please forward information to: Sara Erickson, RD, CSR, LDN, CNSC saraericksonrd@gmail.com

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Remember to update your profile electronically in the 'members only' section of ADA's web site. You will need your registration number and web password. Keeping ADA informed of your name and contact information will help avoid delayed issues of your Renal Nutrition Forum.

### From the Editor's Desk

### Sara Erickson, RD, CSR, LDN, CNSC Editor



It is so exciting to introduce myself as the new editor for the RNF! What a valuable learning experience that has introduced me to so many amazing fellow Renal Dietitians. As Maya Angelou once said,

"When you give, you get" and this could not be more true in regards to my time with the RPG. As many of you might relate, working as the sole dietitian in a program can become isolating at times. Two of the greatest gifts the RPG has given me are a sense of belonging and increased sense of community within the field of nephrology nutrition. Through the RPG we are able to share knowledge and experience with each other, providing a network that is a beneficial resource. Article contributions are a vital part of this network of communication that is provided by the *Renal* Nutrition Forum. I hope that you, a valued RPG member, will consider sending us topic suggestions and comments as your feedback is always welcome. If there is a particular topic of interest to you or perhaps you have attended a conference, such as the recent ADA FNCE, and would like to share your experience with others, please consider submitting an article as there is always a need for subject matter.

In this issue, there are 4 CPEUs available. Our featured article, co-authored by Jennifer Moore, MS, RD, CSR, NSCA-CPT and Roschelle Heuberger, PhD, RD, expands on the benefits of a vegetarian low protein diet supplemented with ketoanalogues for the Chronic Kidney Disease patient population. This informative review focuses on the importance of nutrition counseling prior to the progression of CKD to dialysis. First time author, Erin Ghaffari, RD, contributed our advanced practice article which provides a detailed account on the nutritional evaluation process of the dialysis patient.

With much enthusiasm we are delighted to offer the first report from a newly developed RPG position, liaison to the ADA House of Delegates. Our HOD Delegate, Pam Kent, MS, RD, CSR, LD, has been involved with the RPG in many different aspects which gives her a unique perspective for this important role.

Also included in this issue are summaries of the NKF 2011 Spring Clinical meeting provided by RPG educational stipend recipients who attended in April. Patti Barba, MS, RD, CSR, provides a synopsis of a cutting edge presentation she attended on phosphate additives and Iris McDuffie, MS, RD, LDN provides a review of her poster presentation on the use of the Nutrition Care Process within dialysis centers. Additionally, celebration of dedicated ADA and RPG members can be found in our member spotlight, which contains much appreciated words of advice from two of our fifty plus year members.

Sincere thanks and gratitude to incoming Managing Editor, Megan Sliwa, RD, LDN and outgoing Managing Editor, Stacey Phillips, RD for your guidance and support through my transition to Editor. I would also like to welcome our new Assistant Editor, Jackie Abels, MA, RD, LD...we are so happy to have you on our team! Finally, thank you to the peer-reviewers who provide invaluable feedback, the authors for their contributions, and to Amy Hess-Fishl, MS, RD, LDN, BC-ADM, CDE, for providing the CPEU test questions. Without you the Forum could not be completed!

Best Regards,

# **Erratum**From Spring 2011:

Please accept our apologies, in the OSA Winner Write-up on page 22 in the Spring 2011 *Renal Nutrition Forum* (Vol. 30, No. 2), the winner's name did not appear correctly. The name should have appeared as 'Philippa Norton Feiertag'.

ara Excesse

Patients with CKD are on a variety of medications such as ACE inhibitors and angiotensin receptor blockers for comorbid conditions. Diabetic CKD patients require oral agents or insulin. These medications are costly and typically have unwanted side effects leading to poor compliance (4-7).

Dietary changes should be standard practice for quality care in CKD, but the USRDS reports that only 3.6 percent of patients see a renal dietitian for a year or more before initiating dialysis. With a total end stage renal disease (ESRD) Medicare expenditure of 23.9 billion in 2007, up 2.6% from the prior year, upstream preventative interventions need to be implemented to reduce the financial and societal burden of CKD (1). Treating CKD should incorporate a vegan, low protein diet that is supplemented with KAs. Each intervention can be viewed independently as being effective, but their combined efficacy suggests further research to establish a best practice of a SVLPD. This nutritional intervention improves uremic symptoms and slows progression of kidney damage without a decline in nutrition status.

### **Vegan Diets and Risk Reduction**

There is epidemiological evidence that a vegan lifestyle can lower the risk of the two main causes of kidney damage, diabetes mellitus (DM) and hypertension (HTN). Hyperlipidemia is also considered a risk factor for CKD and is a common co-morbidity of DM. Lipid abnormalities, DM, and HTN are improved with a vegan diet through mechanisms including, but not limited to, decreased intake of saturated fat and cholesterol, increased fiber intake, increased plant sterol intake, improved vascular dilatory responses, and improved insulin sensitivity. Evidence suggests that hyperlipidemia and atherosclerosis are not only improved, but even reversed with a vegan lifestyle (8,9). The following sections will elucidate the evidence for the effect of veganism on DM, HTN, and cardiovascular disease (CVD).

### Diabetes- The Main Cause of CKD

Worldwide, in the year 2000, it was estimated that 154 million people had diabetes-induced kidney disease. The estimation for the year 2030 is 370 million globally. One explanation for the burden of diabetes around the world is the growing obesity rates and their association with type 2 diabetes. Type 2 patients develop kidney disease much the same as type 1 patients. Diabetes prevention is tantamount but once patients develop the disease, maintenance of tight glucose control is of utmost importance (10). Tight glucose control and lowering of body weight are the cornerstones of DM complication prevention.

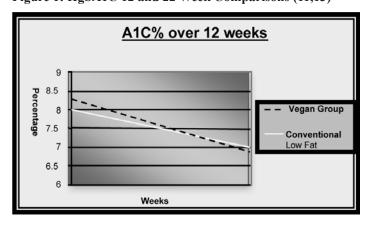
It is well known that vegans have lower body weights than omnivores (8). Vegan diets are an effective preventative measure for obesity, and subsequently, DM. There is research supporting the positive effects of a vegan diet in the treatment of DM. There is also research supporting vegan diets in the prevention of risk factors for developing DM such as hyperinsulinemia (11,12).

A pilot study was conducted by Nicholson et al, to examine whether a plant-based diet could improve glycemic control in non-insulin dependent diabetes mellitus (NIDDM). Eleven participants with NIDDM, ages 25 years and older, were randomly assigned to either a low fat vegan diet or a conventional low fat diet for 12 weeks. The protocol included twice weekly support groups which included cooking and nutrition classes along with a group meal. Laboratory tests including fasting serum glucose, hemoglobin A1C, serum lipids and urinary microalbumin were obtained. Subjects completed 3-day diet records at baseline and at the 3 month follow up. The diet records included two weekdays and one weekend day. Adherence was assessed through selfreport questionnaires that were handed out at group meals. The results included a 28% mean reduction (195 to 141 mg/dl) in fasting serum glucose (FSG) in the vegan group which was significantly greater than the 12% mean reduction (179 to 157 mg/ dl) for the control group (p=0.005) (13).

A similar study was carried out on 99 type 2 diabetics randomly assigned to a low fat vegan diet or a diet adhering to the American Diabetes Association (ADA) guidelines. No meals were provided, but each subject consulted with a registered dietitian (RD) for one hour to establish an appropriate diet plan. This was followed up with weekly one hour meetings, nutrition and cooking classes and an appointment with a physician, RD, and/or a cooking instructor. Dietary compliance was monitored by unannounced telephone calls from the RD. Additionally, three day diet records were obtained from each subject at weeks 0, 12, and 22, reflecting two weekdays and one weekend day. Forty-three percent of the vegan group and 26% of the ADA group had a reduction in diabetic medications. Results, when excluding those with reduced medications, showed a drop in hemoglobin A1C by 1.23 points in the vegan group compared with 0.56 in the ADA group (p = 0.089). When including all participants, a drop in A1C by 0.96 percentage points in the vegan group compared with 0.38 percent points in the ADA group (p = 0.01). Body weight in the vegan group decreased 6.5 kg in the vegan group and 3.1 kg in the ADA group. Body weight change correlated with A1C change (r = 0.51, P < 0.0001) (11).

In both trials, positive results were seen with the vegan diet. For instance, in the pilot trial, a 28% decrease was seen in fasting serum glucose of the experimental vegan group as opposed to only a 12% decrease in the control omnivorous group. The effect on hemoglobin A1C was not significant in this study. In the larger study, subjects whose medications remained stable throughout the study showed significant changes in fasting serum glucose and hemoglobin A1C. Results combined from the two studies are depicted in Figures 1 and 2. In addition to the effects for diagnosed diabetics, there may be a role for vegan diets to suppress insulin resistance syndrome.

Figure 1: HgbA1C 12 and 22 Week Comparisons (11,13)



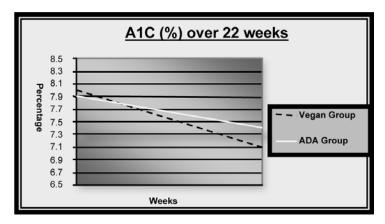
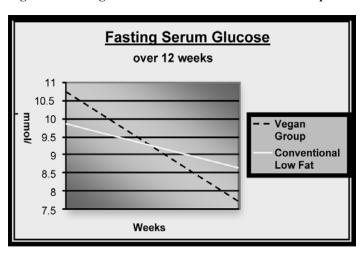
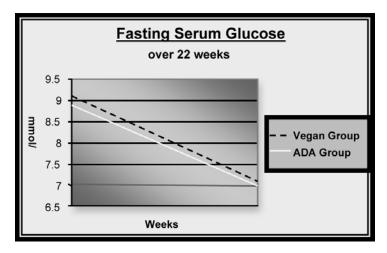


Figure 2: Fasting Serum Glucose 12 and 22 Week Comparisons (11,13)





### Insulin Resistance

Insulin resistance precedes the onset of DM which impacts the CKD population. Three studies comparing the difference in insulin sensitivity between vegetarians/vegans and omnivores were reviewed. Each study examined insulin resistance through the Homeostasis Model Assessment for Insulin Sensitivity (HOMA-IR) and showed higher insulin sensitivity in the vegetarian group as seen in Table 1 (14-16).

### Hypertension

DM and HTN are often comorbid. Greater than 70% of type 1 diabetics and 90% of type 2 diabetics are also hypertensive (10). One in three dialysis patients in 2007 had HTN listed as the cause of kidney failure (1). Vegetarians/vegans have lower than average blood pressure (BP) than omnivores and BP in vegetarians/vegans does not rise significantly with age (17). Lindahl et al, followed 29 patients with established, hospital

verified, long-term HTN. They followed a vegan diet for one year. All of the patients were dissatisfied with the side effects of the antihypertensive medications and held a common fear of being on lifelong medication. Significant improvements in BP were seen with the adoption of the vegan diet. Of the 26 patients in the study, 20 had their antihypertensive drugs discontinued and 6 lowered their dose, usually by half (18). Table 2 shows results for the decrease in BP.

### Cardiovascular Disease

Lipid abnormalities are common with kidney damage and persistent proteinuria. These abnormalities not only promote atherosclerosis, but a more rapid progression of kidney disease (19). The National Kidney Foundation's Kidney Disease Outcome Quality Initiative (K/DOQI) guidelines state that all CKD patients are in the "highest risk" group for CVD. Due to prevalence of traditional (lipid abnormalities) and nontraditional (CKD related calcium deposition) causes of CVD, 40% of patients present to ESRD clinics with evidence of CVD. Once renal

replacement therapy is initiated, CVD accounts for 40-50% of deaths in ESRD patients (20). Numerous studies have documented the effectiveness of a vegan diet in the prevention and even improvement of cardiac risk factors and atherosclerosis. Though recommendations for the American Heart Association (AHA) diet have moved toward the Dietary Approaches to Stop Hypertension (DASH) diet, the Lifestyle Heart Trials represent a valid argument for vegan/vegetarian diets to treat and reverse atherosclerosis. Dean Ornish, MD conducted the Lifestyle Heart Trials where 48 subjects were randomized into a strict vegetarian diet comprised of 10% of calories as fat and 4mg cholesterol daily and a control group. Protocols included moderate exercise, stress management, smoking cessation, and group psychosocial support. The control group followed the standard AHA recommendations of no red meat, only skinless chicken, and fish with 30% of calories as fat and 300mg of cholesterol daily. Moderate exercise was recommended but stress management was not included for the control group. Subjects in the treatment arm saw complete or nearly complete resolution of angina and sclerosis in 82% of patients. Subjects following AHA guidelines saw an increase in chest pains and arterial blockages worsened significantly (9). Follow up to this study was completed at one year and five years. More improvements were seen in regression of coronary atherosclerosis after five years than one year in the experimental group indicating not only long term adherence to the program, but also a continued effect on improved CVD risk factors (21).

Table 1: Insulin sensitivity between vegetarian and omnivorous groups (14-16)

	n	Average Age (years)	Mean HOMA-IR	Significance
Hung C, et al	49	36.6	1.09	
Vegetarian				p = <0.001
Omnivore	49	36.9	1.73	
Kuo C-S, et al	42	58.6	4.78	
Vegetarian				p = 0.002
Omnivore	50	55.7	6.75	
Valachovicova M, et al	95	37.8	.99	
Vegetarian				p = <0.001
Omnivore	107	38.7	1.59	

### **CKD and Vegetarian Nutrition-Source of Protein Debate**

Research supports the nutritional management of chronic diseases that cause kidney damage and the replacement of animal with soy protein when damage has already occurred. A vegan diet, especially a vegan soy diet, has been shown to reduce urinary albumin excretion and disease progression. Type 2 diabetics with microalbuminuria who replaced red meat and chicken with soy and made no changes in the amount of protein eaten showed reduced albumin excretion rates (22,23). Additionally, replacing animal protein with soy protein has been shown to reduce urinary urea nitrogen, serum phosphorus, glomerular filtration rate (GFR), and

Table 2: Changes in blood pressure before and after therapy (18)

	Period of Therapy (Months)	Before Therapy Mean (mmHG)	After Therapy Mean (mmHG)	Statistical Significance
	0-4	151	144	p = <0.05
Systolic Blood Pressure	0-12	151	142	p = <0.01
	0-4	88	78	p = < 0.01
Diastolic Blood Pressure	0-12	88	83	p = <0.05

renal plasma flow (24,25). Improvement in these parameters, particularly proteinuria (since a high level of proteinuria is associated with a faster decline in renal function), warrants the use of plant sources in the management of patients with CKD. In addition to changing the type of protein, limiting the amount of protein should be considered.

## Low Protein Diets – This Historical Standard of Care Became Unpopular

Lowering the amount of total protein intake is an integral component in the management of CKD. This intervention has become uncommon in the US and Europe where 0.8 g protein/kg body weight is more often prescribed (26). Even with this higher protein recommendation, 44 % of patients are still initiating renal replacement therapy malnourished per serum albumin, prealbumin and anthropometrics. Low protein diets (LPD) and supplemented low protein diets (SLPD) have been used for four decades and should be revisited (26). Dietary protein restriction in CKD decreases the accrual of unexcreted waste products while preventing decline in nutritional status. It is known that an increase in renal blood flow and GFR of approximately 20-28% is seen two hours post ingestion of a protein or amino acid load (27). Despite the fact that the K/ DOQI guidelines recommend a protein limitation of 0.6-0.75 g/ kg of body weight (BW) in CKD patients, protein restriction is many times no longer advised (2).

Patients with CKD commonly have a spontaneous reduction in appetite, protein intake, and a natural aversion to meat as they progress through the stages of CKD. Purposefully restricting protein as a strategy to slow progression in a way that is monitored and controlled benefits the patient by alleviating the uremic symptoms that are causing the decline in intake, decreasing proteinuria, and lessening the strain on the kidneys. Dr. Shanyan Lin, Professor of Medicine, Division of Nephrology, Shanghai Medical University Hua Shan Hospital, states, "A Low-protein diet is a very realistic, effective and efficient way to retard the progression of CKD. It is comparable to even the most advanced way to treat CKD with drugs like ACE inhibitors or angiotensin receptor blockers." Despite evidence displaying the benefit of protein restriction in CKD, negative notions still exist.

### **MDRD Study**

The negative view toward protein limitation in CKD is likely a result of the Modification of Diet in Renal Disease (MDRD) study, a multicenter trial to test the efficacy of protein restriction and BP control on the progression of kidney damage. The MDRD study is the largest study to date that has investigated the

efficacy of protein restriction in patients with CKD. The failure of this study to demonstrate a beneficial effect of protein restriction has been interpreted as proof that this therapy does not slow progression of the disease. The study, however, was inconclusive and had many limitations. First, evidence of progressive kidney disease did not have to be proven in order for patients to be enrolled. Approximately 15% of the Study A control group had no decline in GFR thus making measurements impossible. Second, study B patients treated with SVLPD had no control group for comparison. Third, polycystic kidney disease (PKD) is unaffected by nutrition interventions and around 20% of patients had PKD. Fourth, ACE inhibitors can mask the benefits of a LPD and patients with high BP were being treated with them in an unregulated fashion. Lastly, a rapid decline in GFR in Study A was unexpected and followed by a slowed progression, so an increase in the duration of the study would have been necessary to see an effect (28). The initial MDRD study was inconclusive but secondary analysis showed greater consistency with preservation of GFR levels with protein restriction on CKD progression (29).

### KA Supplementation-A Missing Addition for Low Protein Diets in the US

Ketoanalogues of essential amino acids (EAAs) have been introduced into the treatment of CKD patients on LPD. This is a more common practice outside the US. KAs lack nitrogen (N) so they do not produce excess uremic waste. However, they can still be converted to EAAs in the liver, muscle, and intestine (30). Benefits of KAs include (31):

- 1. Aids in the preservation of nutrition status.
- Aids in the alleviation of uremia by capturing excess N residues and utilizing them for the production of AAs. As a result, dietary protein can be restricted and formation of endogenous urea declines, both of which lessen the work load on the kidneys.
- 3. Stimulates protein synthesis and inhibits protein degradation.
- 4. Decreases proteinuria thus causing a rise in serum albumin (ALB).
- 5. Does not induce hyperfiltration in the kidneys.
- Improves carbohydrate metabolism abnormalities seen in uremia through enhanced tissue sensitivity to insulin and decreased circulating insulin levels which is advantageous in diabetic nephropathy.
- 7. Improves lipid abnormalities by decreasing triglycerides (TG) and increasing high density lipoprotein (HDL) levels.

With additional research, a LPD that is plant based and supplemented with KAs will likely prove to be a best practice in the nutritional management of CKD patients.

### **Outcomes of a SVLPD - Putting it All Together**

Research indicates the most effective treatment strategy for CKD patients is a SVLPD. Of the four SVLPD studies reviewed, the dietary protein intake ranged from 0.3 g/kg BW to 0.7 g/kg. Each group was treated with Ketosteril which is a supplement containing Ketoanalogues (Nitrogen free EAA) and EAAs. Calorie ranges were 30-35 kcal/kg BW (30-34). These results are summarized below.

### Population Size (n)

<u>Prakash et al</u>: 34 renal patients randomly assigned to two groups by study coordinator. Group 1 (n=16): 0.6 g/kg/d protein plus placebo. Group 2 (n=18): 0.3 g/kg/d protein plus Ketosteril.

Eyre et al: 122 renal patients were recruited from the dialysis registry of one clinic. SVLDP group (n=61): 0.6g/kg/d, Control Group (n=61).

<u>Barsotti 1990</u>: 13 nephrotic patients on unrestricted protein diets were given 0.7 g/kg/d protein with keto/amino acid supplementation. <u>Barsotti 1991</u>: 20 nephrotic patients recruited from Outpatient Renal Service to follow 0.7g/kg/d protein diet with keto/amino acid supplementation.

### Glomelular Filtration Rate (GFR)

Two of the four studies had GFR as an outcome measure. In both of these studies significant decline was seen in the control/placebo groups that were not treated with the SVLPD. Those on the SVLPD maintained GFR rates over time. The following is a summary of GFR (mL/min/1.73m²) levels from two of the studies:

#### Prakash et al:

Placebo: pre-trial 28.6 (+/- 17.6) post-trial 22.5 (+/- 15.9)

(p=0.015)

Ketodiet: pre-trial 28.1 (+/- 8.8)

post-trial 27.6 (+/- 10.1)

(p=0.716)

### Eyre et al:

Control Group: 15.7 (initiation), 14.1 (6m predialysis), 7.4 (3m

predialysis), 6.7 (1m predialysis), 4.1 (dialysis)

SVLPD Group: 9.9 (initiation), 9.2 (6m predialysis), 5.8 (3m predialysis), 6 (1 months (m) predialysis), 4.7 (dialysis)

#### Serum Creatinine (Cr)

One of the four studies compared serum Cr levels between the two nutritional interventions. The placebo group showed significant increase in serum Cr while the ketodiet group showed no significant increase. Barsotti et al changed patients from a low sodium diet (LSD) to a SVLPD with no significant increase in serum Cr. The serum Cr (mg/dL) changes are as follows:

#### Prakash et al:

Placebo: pre-trial 2.37 (+/- 0.9)

post-trial 3.52 (+/- 2.9) (p=0.066)

Ketodiet: pre-trial 2.26 (+/- 1.03)

post-trial 2.07 (+/- 0.8) (p=0.90)

Barsotti, 1991 et al: LSD: 0.8 (+/- 0.2)

SVLPD 0.8 (+/- 0.2)

(p=not significant)

#### Proteinuria

Urinary protein excretion was evaluated in the two studies by Barsotti and colleagues. Both revealed significantly less protein excretion in the SVLPD groups. The difference in urinary protein excretions are as follows:

Barsotti, 1990 et al: Unrestricted protein diet: 8.7 (+/- 2.6) g/day

SVLPD: 5.6 (+/- 2.4) g/day (p<0.01)

Barsotti, 1991 et al: LSD: 7.6 (+/- 2.3) g/day

SVLPD: 5.5 (+/- 1.9) g/day (p<0.01)

### Dialysis Delay

An additional outcome of dialysis delay was investigated in a separate study. Results of a retrospective study of 122 renal patients showed that dialysis can be delayed by as much as six months with a SVLPD (34). Additional research in elderly renal patients showed that for those who were willing to follow a SVLPD, dialysis was delayed for up to one year (35).

### **Markers of Nutritional Status in CKD**

#### Anthropometric Measures

When observing the effect of a SVLPD on nutrition status, assessment tools include body mass index (BMI), mid-arm muscle circumference (MAMC), and triceps skinfold (TSF). Barsotti and colleagues conducted two studies with CKD patients placed on a vegan diet with 0.7 g/kg body weight of protein plus ketoacid supplementation and 30 kcal/kg. (32,33). Prakash and colleagues conducted a study where patients were placed on 0.6 g/kg protein or 0.3 g/kg vegetable protein supplemented with ketoacids; both at 30-35 kcal/kg (30). Results of each of these studies showed no adverse effects of protein restriction on anthropometric measures. Figure 3 depicts the anthropometric measures seen with the different diet therapies. Control diets and SVLPD had no differential impact on anthropometrics or nutritional status.

### Serum Albumin (ALB)

A criticism of SVLPD is limiting the protein intake of CKD patients may increase the risk of hypoalbuminemia, especially in combination with proteinuria. The results of these trials show no significant declines in serum ALB. In the two studies by Barsotti and colleagues, ALB levels increased from 2.6 to 2.9 g/dl. Prakash and colleagues showed serum ALB levels in the placebo group to

be lower (3.84 g/dl +/- 0.36) versus the ketodiet group (3.98 g/dl +/- 0.59) (30,32,33). Although the difference is not statistically significant, these studies still support SVLPD as maintaining adequate protein nutriture in CKD.

#### Metabolic Acidosis and Malnutrition

Metabolic acidosis leads to malnutrition in CKD patients. The pH of blood is tightly controlled in the range of 7.35-7.45. Uremic acidosis is typically present in CKD, and is associated with increased protein catabolism and negative nitrogen balance (36). In the healthy population, acidity is affected mainly by medications and diet. Studies have confirmed that the urine of omnivores is significantly more acidic than that of vegans. High animal protein diets are associated with increased urinary saturation with uric acid. When on an acidic diet, patients with CKD sustain an increase in blood urea nitrogen (BUN) reflecting not only a high protein intake but also increased catabolism of endogenous protein (37,38).

In a study of 70 patients with advanced CKD (GFR<15 mL/min/1.73m²) subjects were either treated with a LPD of 0.6 g/kg body weight of protein or a SVLPD of 0.3 g/kg body weight supplemented with EAAs and KAs. Fifty-two healthy matched controls were given a regular diet. Subjective Global Assessment (SGA) was used to measure nutritional status. The results revealed no evidence of severe malnutrition and abnormal parameters were rare in the patients treated with the SVLPD. On the other hand, SGA abnormalities were seen in patients with lower serum bicarbonate levels and higher serum urea levels reflective of higher protein intake (37).

### **Compliance**

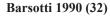
In a literature review from 2003-2008, studies indicate that compliant patients benefited from LPD in various ways including decreased proteinuria and improved serum albumin and bicarbonate levels (23). Compliance and adherence to a SVLPD in CKD is an obvious prerequisite for efficacy. Documented compliance to diets with decreased protein was 42% and 51% of patients enrolled (39). Vegan nutrition has been shown to be comparable in acceptability and adherence in type 2 diabetics and premenopausal women (40,41). Two successive studies demonstrate 67.5% and 70% compliance with a SVLPD (34).

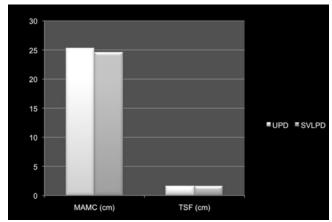
Additionally, there is evidence that society is at a place of openness toward vegan diets or at the very least limiting animal protein consumption. The acceptability of the health benefits of veganism is seen by the number of professional and lay journals that deal with the topic. It has also been frequently presented on the front page of international magazines such as Newsweek and Time (42). Studies have shown that acceptability of vegan diets compares with other medically recommended diet changes (39).

#### **Cost of Prevention**

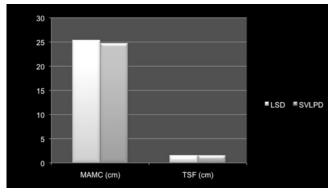
Employment of renal dietitians and financial coverage of KA therapy may be an argument against such nutritional interventions for CKD. That being said, a chronic disease that involves the use of a machine to extend life, sometimes by decades is a costly one. Section 2991 of the

Figure 3: Nutrition Interventions and Anthropometry (30,32,33)

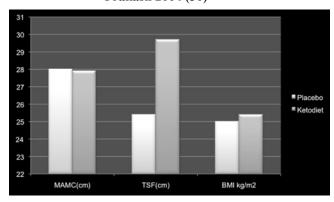




Barsotti 1991 (33)



Prakash 2004 (30)



BMI: Body Mass Index; LSD: Low Sodium Diet; MAMC: Mid-Arm Muscle Circumference; SVLPD: Supplemented Vegan Low Protein Diet; TSF: Triceps Skinfold; UPD: Usual Protein Diet

Social Security Amendment of 1972 entitled patients with ESRD to receive dialysis or transplantation if they qualified for Medicare. The first Medicare hearing after this entitlement held in 1975 found the cost of the program was much higher than had been predicted. The enormous expense of the program has become problematic (40). The costs associated with renal replacement therapy include but are not limited to medical staff, numerous home and in-center medications, supplies for treatment, and frequent hospitalizations. The first month a patient initiates dialysis costs \$15,000 for Medicare patients and \$32,000 for those with private health insurance. Considering 99,886 patients initiated hemodialysis and 6,376 initiated peritoneal dialysis in 2007, the first month costs reach over one billion dollars. This does not include any hospitalizations or loss of work force (1).

When viewed on a per patient per year basis, Medicare costs alone rose to \$70,581 reaching a total of \$24 billion (1,43). As stated above, research has shown a delay in the need for dialysis in patients following a SVLPD for 6 months to a year (35). When viewed from a Medicare spending standpoint, this delay could save around \$85,581 per patient considering initiation and yearly costs.

Ketosteril, however is not made in the US and is expensive. Fresenius Kabi, a German company, makes the supplement and the cost of 100 tablets is approximately \$2,605.72 (44).

#### Conclusion

Transitioning from curative medicine toward prevention for CKD is imperative. A SVLPD monitored by a renal dietitian achieves the goal of providing effective treatment for CKD patients. It reduces the accumulation of waste products, lessens kidney strain, and prevents malnutrition. Nutritional care for CKD stages 1-4 is suboptimal at best in the US. While diabetics and ESRD patients are instructed and monitored, a gap in care for CKD patients exists. This is evidenced by the lack of multidisciplinary CKD clinics in our nation and few nephrologists who employ dietitians. Only 3.6% of patients have worked with a renal dietitian for one year prior to dialysis and 90% received no dietary counseling at all prior to dialysis (1). A SVLPD administered by a renal dietitian is a best practice for nutritional intervention in CKD. Establishment of SVLPD treatment plan guidelines needs to occur, along with increased training of renal dietitians on implementation to ensure the vegan diet is comprised of whole foods as opposed to low protein, vegan foods that have little nutritional value. CKD patients should see a multidisciplinary team that includes a renal dietitian on a consistent basis since routine follow up improves adherence (45,46). Current research regarding ketoanalogue therapy should be scrutinized more closely by nephrologists and primary care physicians who see CKD patients for possible integration into their practices. Additional research is required to quantify the degree of efficacy of a SVLPD, thus justifying the costs. Lobbying should be done for funding to treat CKD much in the same way it was done in 1972 for ESRD. Cost savings, and life savings, either through extension of survival or the quality of life justifies continued investigation. Any therapy that

delays or prevents dialysis, such as SVLPD should be aggressively pursued.

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