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ORIGINAL ARTICLE

Treatment of chronic kidney disease patients with ketoanalogue-supplemented low-protein diet and ketoanalogue-supplemented very-low-protein diet

S.V. Subhramanyam, V. Lakshmi, K.S. Nayak*

Deccan Institute of Nephrology and Renal Transplantation, Raj Bhavan Road, Somajiguda, Hyderabad 500082, Telangana, India

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residual renal function

Summary *Introduction:* A low-protein diet supplemented with ketoanalogues (KAs) has been shown to be effective in improving the benefits of a low-protein diet for patients with chronic kidney disease (CKD).
Materials and methods: A total of 178 adult patients with CKD Stages 3–5 (predialysis) were assessed for 1 year. A total of 122 patients were in the KA-supplemented low-protein diet (sLPD) group and were prescribed 0.6 g/kg body weight (BW) of dietary proteins supplemented with one KA tablet for every 10 kg BW. The remaining 56 patients were in the KA-supplemented very-low-protein diet (sVLPD) group and received 0.3 g/kg BW of dietary protein supplemented with one KA tablet for every 5 kg BW. Renal, metabolic, and nutritional parameters, and anthropometric assessments were performed for all patients.
Results: We assessed the renal function of the patients. There was no difference in the baseline clinical and laboratory characteristics between the sLPD and sVLPD groups. In the sLPD group, the blood urea level decreased from 85.38 ± 4.45 to 76.90 ± 42.90 mg/dL ($p < 0.05$) after 12 months. CKD stagewise assessment of the 24-hour urinary creatinine clearance (CrCl) showed an improving trend of renal function. In the sVLPD group, the blood urea level after 6 months decreased from 98.38 ± 42.97 to 79.84 ± 34.15 mg/dL ($p < 0.05$), but it increased to 102.74 ± 45.98 mg/dL ($p > 0.05$) at the end of 1 year. The CrCl showed a marginal increase at the end of 1 year, but this increase was not statistically significant. There was a decrease in urinary protein excretion in both groups. Anthropometric measurement, including Subjective Global Assessment, showed nutritional improvement in both groups. Pearson correlation coefficient between protein intake and urinary nitrogen appearance showed positive correlation between the two groups.

* Corresponding author. Deccan Institute of Nephrology and Renal Transplantation, Raj Bhavan Road, Somajiguda, Hyderabad 500082, Telangana, India.
E-mail address: drksnayak@gmail.com (K.S. Nayak).

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Conclusion: The CKD patients on sLPD and sVLPD showed improvement in renal function, metabolic status, and nutrition.
方法: 研究對象為 178 位 3—5 期(透析前)慢性腎病成年患者，其中 122 人接受酮類似物 (KA) 補充之低蛋白飲食 (sLPD)—含每公斤體重 0.6 g 蛋白質及每 10 公斤體重 1 顆 KA 錠；另 56 人接受 KA 補充之極低蛋白飲食 (sVLPD)—含每公斤體重 0.3 g 蛋白質及每 5 公斤體重 1 顆 KA 錠。治療期間的測量項目包括腎功能、代謝、營養學、體格等方面的變化。
結果: 在各項基線臨床及化驗特徵上，sLPD 及 sVLPD 兩組之間無明顯差異。經過 12 個月後，sLPD 組的血中尿素從 85.38 ± 4.45 mg/dl 下降至 76.90 ± 42.90 mg/dl ($p < 0.05$)，24 小時尿液肌酸酐清除 (CCT) 則顯示，在各級腎病患者中，腎功能呈現改善傾向；至於 sVLPD 組，6 個月的血中尿素從 98.38 ± 42.97 mg/dl 下降至 79.84 ± 34.15 mg/dl ($p < 0.05$)，然後於 12 個月增加至 102.74 ± 45.98 mg/dl ($p > 0.05$)，12 個月的 CCT 則呈現增加的傾向。在兩組的病人間，尿液蛋白排泄量均明顯下降，體格方面的測量包括 SGA 均呈現營養狀況的改善。兩組間，以 Pearson's 系數分析可見，蛋白質攝取量與尿液氮出現量呈現明顯的相關性。
結論: 慢性腎病患者在接受 sLPD 及 sVLPD 期間，腎功能、代謝及營養狀況均呈現出穩定化的情形。

Introduction

Low-protein diets have been one of the cornerstones in the management of chronic kidney disease (CKD) for more than five decades. Apart from mitigating the accumulation of nitrogenous wastes and metabolic disturbances, both of which are characteristic of advanced stages of CKD, such diets also reduce the quantities of sulfates, phosphates, potassium, and sodium ingested, thus leading to a more favorable metabolic profile. Several meta-analyses have indicated the beneficial effect of low-protein diets in retarding the progression of CKD.[1—3]

Materials and methods

The study included 178 adult patients (CKD Stages 3—5; predialysis). The patients received a protein-restricted ketoanalogue (KA)-supplemented diet after obtaining informed consent and the necessary Institutional Ethics Committee approvals. Based on their affordability, 122 patients were randomly assigned to the KA-supplemented low-protein diet (sLPD) group. The patients in this group received 0.6 g/kg body weight (BW) of dietary protein supplemented with KAs at a dose of one tablet/10 kg BW. The remaining 56 patients received 0.3 g/kg BW of dietary protein supplemented with KA at a dose of one tablet/5 kg BW and these patients constituted the KA-supplemented very-low-protein diet (sVLPD) group. Renolog tablets (La Renon Healthcare, Ahmedabad, Gujarat, India) were prescribed as the KA supplement. Renal, metabolic, and nutritional parameters, and anthropometric assessments (using the Harpenden Skinfold Caliper, Baty International, West Sussex, UK) were performed in both groups at the start of the study, at 6 months, and at the end of 12 months.

A skilled and dedicated renal nutritionist ensured the validity of the dietary and nutritional monitoring and assessments protocol. Because we had no control on those untreated with KAs, we compared the treated group with a hypothetical group whose initial renal parameters were taken as the mean of the values of all patients in the study group and the end of study values were taken without modification from the start of the study values.[4] This inherently would weigh against the KA study group in the interpretation (i.e., renal function changes), as we would normally expect decay of renal function during the 6-month treatment period. Another confounding issue in taking a control group was the unpredictable uniform decline in renal function that occurs in patients with different CKD etiologies. A diabetic nephropathy would probably deteriorate three times faster than would a benign nephrosclerosis.

Nutritional assessment included measurement of weight, body mass index (BMI), waist circumference, hip circumference, waist-to-hip ratio (W/H). In addition, we also measured the mid-arm circumference (MAC), skin-fold thickness (SFt of biceps, triceps, subscapularis, and suprapinatus), subcutaneous fat (SF of limbs, trunk, visceral fat, and whole body), skeletal muscle (SM of limbs, trunk, and whole body), and Subjective Global Assessment (SGA) scores in both groups.

Results

A total of 122 patients were recruited in the sLPD group, of which six shifted to dialysis therapy. None of the patients in the sLPD group underwent renal transplantation during the study period. In the sVLPD group, 54 were recruited, of which six shifted to dialysis therapy and two underwent renal transplantation. Decision for dialysis therapy not only varies to some extent from one center to another, but also depends on the willingness and affordability of the patient, especially in a developing country like India, where patients have to pay for their treatment. The approximate cost of KA supplementation/month for an sLPD patient in India is US$175 and the cost of KA supplementation/month for an sVLPD patient is US$350. Because the cost of sVLPD therapy is almost the same as that of dialysis therapy, many patients in the sVLPD group shifted to dialysis therapy. A comparison of the baseline clinical and laboratory characteristics between the sLPD and sVLPD groups, as presented in Table 1, showed no difference in the weight, BMI, resting metabolic rate (RMR), SGA score, protein intake,