1: J Ren Nutr. 2004 Apr;14(2):89-96.
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Randomized, double-blind, placebo-controlled trial to evaluate efficacy of ketodiet in predialytic chronic renal failure.

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OBJECTIVE: To assess whether a ketodiet, a combination of ketoanalogs of essential amino acids (KAs) and a very low-protein diet, retards progression of chronic renal failure and maintains nutritional status. DESIGN: A prospective, randomized, double-blind, placebo-controlled trial. SETTING: Nephrology outpatient department in Northern Railways Central Hospital, New Delhi, India. PATIENTS: Thirty-four patients in predialytic stages of chronic renal failure (CRF), randomized to 2 comparable groups in terms of age, sex distribution, blood pressure control, etiology, use of angiotensin converting enzyme inhibitors, serum creatinine, glomerular filtration rate (GFR), and body mass index (BMI). INTERVENTION: Subjects randomly received either 0.6 g/kg/d protein plus placebo (n = 16) or 0.3 g/kg/d protein plus tablets of KAs (Ketosteril; Fresenius Kabi, Germany) (n = 18) for 9 months. A dietician administered the diet as well as the KAs or the placebo to the patients. OUTCOME MEASURES: Changes in GFR and renal and nutritional parameters were measured. RESULTS: Mean (+/- SD) GFR measured by the 99mTc-DTPA (99 m technetium diethylenetri-aminepenta-aceticacid) plasma sample method was unchanged in the ketodiet group: 28.1 +/- 8.8 (before) and 27.6 +/- 10.1 mL/min/1.73 m2 (after the study) (P =.72). However, it significantly decreased from 28.6 +/- 17.6 to 22.5 +/- 15.9 mL/min/1.73 m2 in the placebo group (P =.015). Serum creatinine before and after the study in the ketodiet group was 2.26 +/- 1.03 mg/dL and 2.07 +/- 0.8 mg/dL (P =.90) and in the placebo group was 2.37 +/- 0.85 and 3.52 +/- 2.9 mg/dL (P =.066), respectively. In both groups the mean BMI did not change from 25.4 +/- 4.2 to 24.5 +/- 4.2 kg/m2 (P =.46) for ketodiet and from 25.0 +/- 6.8 to 23.9 +/- 4.1 kg/m2 (P =.39) for the placebo group. Serum total proteins decreased significantly (P =.038) in the placebo group, and serum albumin showed a trend (P =.061) toward reduction,

whereas both of these parameters were maintained in the ketodiet group. CONCLUSION: Over a 9-month period, very low-protein diet supplemented with ketoanalogs helped CRF patients to preserve GFR and maintain BMI. KAs were safe and efficacious in retarding the progression of renal failure and preserving the nutritional status of CRF patients.

Publication Types:

- Clinical Trial
- Randomized Controlled Trial

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