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Dietary Supplementation with Probiotic Formulation (Kibow Biotics®) on CKD III and IV patients – a Short Term Pilot Scale Study in Canada

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1. AIM

To assess the biochemical and clinical effects of probiotic bacteria selected and formulated to metabolize nitrogenous waste in patients with chronic kidney disease (CDK) state 3 and 4.

2. METHOD

A prospective, randomized, double blind, crossover, placebo controlled, 6-month trial of probiotic bacteria was conducted in 16 outpatients in Ontario, Canada. Primary endpoints included effect on hematologic, biochemical, and fecal variables, and on general well-being as assessed by quality of life (QOL). These outcomes were evaluated from biochemical parameters, mainly blood urea nitrogen (BUN), creatinine, uric acid, and C-reactive protein (CRP) as a general inflammatory marker. QOL was assessed on a subjective scale of 1 to 10 as the secondary parameter.

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3. RESULTS

Summary of Significant Changes in Treatment Group

Biochemical Parameters

- Uric Acid, delta change -24.70 µmol/L (p=0.050)
- BUN, delta change -2.93mmol/L (p<0.05)

Quality of Life

- Increased by 1.09 points, in 1 to 10 scale (p<0.05)

Fecal Analysis

- Fecal pH, delta change -0.35 units (p<0.05)

Table 1. Summary of significant changes in the treatment group.

A total of 13 patients completed the study. Three patients dropped out: one was the receiver of a transplant. The second dropped out for unknown reasons and the third died of myocardial infarction (unrelated to probiotic bacteria or the protocol).

Among the 13 patients who completed the trial, the mean change in BUN concentration during the probiotic treatment period (–2.93 mmol/L) differed significantly (p=0.002) from the mean change in BUN concentration during the placebo period (4.52mmol/L).

In addition, the mean changes in uric acid concentration were moderate during the KB period (-24.70 µmol/L) versus during the placebo period (50.62 µmol/L, p=0.050), and the changes in serum creatinine concentration were insignificant. The average fecal pH of the probiotic bacteria cohort (pH = 6.94) was significantly lower than the placebo cohorts (pH=7.29) with a p=0.05 [1]. Neither gastrointestinal nor infectious complications were noted in any subject with improved QOL.

4. CONCLUSION

Orally administered probiotic bacteria selected to metabolize nitrogenous wastes may be tolerated for as long as 6 months. A major limitation of this trial is its small size that may have precluded detection of changes in other biochemical or hematologic parameters that would be evident in larger cohorts. Extension of the evaluation of this probiotic bacterial mixture will further include a dose escalation trial (Mayo Clinic, Rochester, MN and Thomas Jefferson University, Philadelphia, PA) in a similar prospective, placebo-controlled, and double-blind study site.

References: [1] Probiotic dietary supplementation in patients with stage 3 and 4 chronic kidney disease: a 6-month pilot scale trial in Canada. Curr Med Res Opin. 2009.25(8):1919-30.