



Case Study of a Patient with Juvenile Diabetes and Nephropathy using a Probiotics as a Dietary Supplement for a Continuous Three Year Period

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Purpose

A test case to validate the long term use, safety and potential benefits of a scientifically developed and clinically tested probiotic dietary supplement on a juvenile diabetic nephropathy individual over a three year period..

Background

Probiotics are increasingly being utilized clinically. Presented here is a case study of a juvenile diabetic nephropathy individual who has been voluntarily taking our company's probiotic product formulation for the last three years and also simultaneously providing the lab data periodically.

Medical History

This individual with Type 1 or Juvenile diabetes for over 49 years was also diagnosed with Nephropathy in 1986. He has been on the following medications: Ramipril, Cozaar and Bumex®. He has been taking insulin injections since he was 10 years old – 1960(1X), 1970(2X) and since 1988 (4X) and on insulin pump since 1996.

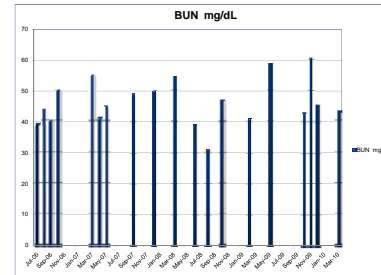
Methodology

As of June 2006, this individual has been taking the probiotic product formulation (currently marketed as a dietary supplement) on his own free will and voluntary basis supplied at no extra cost. The dosage was 2 capsules three times a day (a total of 90 billion CFU's/day)

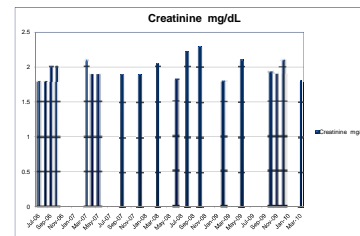
Results

- Several lab parameters were evaluated and graphed.
- Among these are the values of: BUN, Creatinine, Uric acid, and overall improved quality of life on a scale of 1 to 5.
- From the lab data provided in the past three years and graphical values observed, one can extrapolate that there is initial reduction and subsequent stabilization of BUN, creatinine and uric acid values.
- The individual also reported improved vigor, work performance and quality of life.

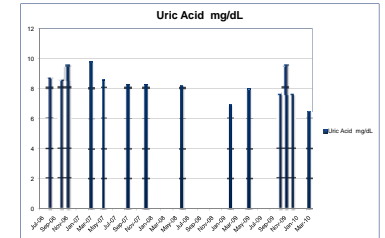
- No noticeable adverse effects were reported in the three years of consuming the probiotic product formulation every day.



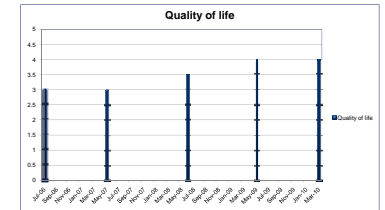
BUN data from July 2006 through March 2010
* Missing data points are due to non-analysis of BUN for that visit



Creatinine data from July 2006 through March 2010
* Missing data points are due to non-analysis of creatinine for that visit



Uric acid data from July 2006 through March 2010
* Missing data points are due to non-analysis of uric acid for that visit



QOL(scale of 1-5) from July 2006 through March 2010
* Missing data points are due to non-analysis for that visit

Conclusion

Daily intake of the probiotic product formulation for a period of three years is safe; helps stabilize and / or maintain key biochemical markers such as BUN, Creatinine and Uric acid and sustains a good quality of life.