

Possible Improvements in GFR of CKD Patients with Renadyl™-3rd Biennial Survey

COMPANY
EXHIBIT
POSTER

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ASN Nov 2-4, 2017
New Orleans, LA

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INTRODUCTION

Probiotics and Prebiotics are seeing wide application in gut related disorders like digestion and immunity. Recent scientific advances have revealed the role of the gut microbiome in various diseases beyond gut health like asthma / allergies, colon cancer / biliary disease, obesity, inflammatory bowel disease (IBD), hypertension / peripheral vascular disease and also the gut-brain axis in autism, anxiety and Parkinson's disease. A prime example of this trend is the burgeoning field of research on gut microbiome and kidney, the **gut-kidney connection**, as well as on various approaches to its modulation using probiotics and prebiotics. We at Kibow Biotech have been working over two decades on developing a probiotic dietary supplement (**GUT-KIDNEY AXIS: KIBOW'S CONCEPT OF "ENTERIC DIALYSIS", USING THE BOWEL AS A SURROGATE KIDNEY**) for the removal of uremic toxins in renal failure patients. The formulation has been studied in a small number of randomized clinical trials for a pharmaceutical like validation. Kibow Biotech's "Enteric Dialysis®" concept based off of the modulation of the gut microbiome to maintain healthy kidney function has proved to be helpful in many of those suffering from CKD. Kibow's product "Renadyl™" has been available since 2010 and is continually being studied to assess just how effective it is. A short survey given to 600 Renadyl customers was distributed to ascertain how their GFR changed, and the impact on their quality of life (QoL) after adding the dietary supplement Renadyl™ into their standard care of therapy.

METHODS

"Renadyl™," a synbiotic dietary supplement was assessed in its ability to maintain healthy kidney function (stabilize GFR), and ability to improve quality of life. A survey was distributed to 600 customers asking for GFR when they began taking Renadyl, and at their most recent doctors visit, as well as age, race, ethnicity, and if Renadyl™ had improved their overall quality of life or not. Statistical analyses were performed on the GFR data to estimate Renadyl's™ impact on GFR, and quality of life. This was done independently analyzed by Alan Weinberg using SAS. Of the 600 surveys sent, 214 (35%) responses were received.

RESULTS

35% (214) of the customers responded.

A) Efficacy as per NKF/FDA guidelines and our data analysis

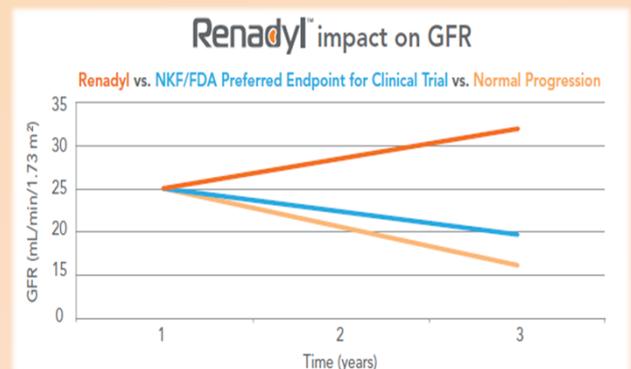
Year	Average Progression of CKD (mL/min/1.73 m ²)	NKF/FDA 40% (Preferred) Endpoint Drug Progression (mL/min/1.73 m ²)	Renadyl GFR (mL/min/1.73 m ²)
1	30	30	30
2	25.6	27.4	32.9
3	21.2	24.8	35.8

RESULTS

B) Efficacy of Renadyl-GFR before and after Renadyl usage

Variable	N	Mean	Std Dev	Minimum	Maximum
gfr1	150	30.521333	17.244093	4	100
gfr2	150	34.074733	20.02078	5	106
diff	150	3.5534	13.240966	-40	65
Yearchange	141	2.9038151	8.4003586	-16	42.222222

C) Renadyl -Possible improvements in GFR



D) Renadyl Satisfaction-QoL

Quality of Life (QoL) by sex			
QoL	Sex		
Frequency Percent (%)	F	M	Total
No	6	18	24
% of M/F	3	9	12
% No by M/F	7.23	15.38	
Yes	77	99	176
% of M/F	38.5	49.5	88
% Yes by M/F	92.77	84.62	
Total	83	117	200
Percent M/F	41.5	58.5	100
Frequency Missing = 14			

CONCLUSIONS

Chronic kidney disease is generally recognized as a degenerative process. However, with over 4,000 customers we sought feedback from 600 of them to assess the impact of Renadyl™ usage over an average of 2.05 years. The longest using participant used the product for 7 years, the shortest for 6 months. **With the ability to stabilize and improve GFR, it may be possible to delay the progression of kidney function decline at all stages.** Improving quality of life in 88% of participants certainly signifies the advantages of using Renadyl™ in patients with compromised renal function worldwide.