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Impact of Gut Microbiome on Quality of Life in Customers with CKD using RenadylTM: Results of a Survey Ranganathan Natarajan^{*}, PhD¹, Ranganathan Parimalam, MS, MT, ASCP¹, D'Silva Henry, MD¹, Vyas Usha, MS¹, Pechenyak Bohdan, MSW/MPH² Weinberg Alan, PhD³. ¹Kibow Biotech, Inc., Newtown Square, PA, USA; ² Temple University School of Medicine, Philadelphia, PA,



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

Employment	N(%)
Employed	31 (18%)

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RESULTS Contd.....



Impact of Renadyl

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 a decade on developing a probiotic dietary supplement (GUT-KIDNEY AXIS: KIBOW'S CONCEPT of "ENTRIC 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. This second survey study aimed to collect information about the impact of gut microbiome modulation with Renadyl[™], a probiotic dietary supplement for kidney function and on quality of life on the health status of current customers with CKD using this product.

	Self-employed			20 (1	2%)	
	Unemployed		8 (5	%)		
		Disabled		9 (5%)		
	Retired			80 (4	8%)	
	Noanswer			20 (1	2%)	
Age at CKD diagnosis (years)						
J			CKD	Stage (GFR)	At start Renady	
<18	(yea			Stage (GFR) No CKD		/
	(yea	irs)			Renady	/
<18	(yea 3 40	rs) 7 (4%)	ا 1 (90	No CKD	Renady 6 (4%)	/
<18 19-4	(yea 8 40 50	rs) 7 (4%) 24 (14%)	ا 1 (90 2	No CKD D> mL/min)	Renady 6 (4%) 9 (5%)	/
<18 19-4 41-5	(yea 3 40 50 50	rs) 7 (4%) 24 (14%) 13 (7%)	ا 1 (90 2 3 م	No CKD D> mL/min) (60-89)	Renady 6 (4%) 9 (5%) 9 (5%)	/ I
<18 19-4 41-5 51-6	(yea 3 40 50 50 70	rs) 7 (4%) 24 (14%) 13 (7%) 32 (19%)	1 (90 2 3/ 3E	No CKD D> mL/min) (60-89) A (45-59)	Renady 6 (4%) 9 (5%) 9 (5%) 27 (16%	/ 6) 6)

	Great improvement	39 (23	3%)	
	Some improvement	63 (37	7.5%)	
	Neutral	47 (28	8%)	
	No improvement	8 (5%)	
	No answer	11 (6.	5%)	
Va	riable	p valı	ue	
Duration of taking Renadyl			< 0.00)01
Employed/Non employed			0.01	114

Variable	p value
Duration of taking Renadyl	< 0.0001
Employed/Non employed	0.0114
Comorbidities	0.0115
GFR	0.0014

A total of 168 responses were received (20% response rate, 42% female, 47% male, aged 12-98 years). A majority (85%) was over 51 years of age, in stage III or IV of kidney disease (58%) with at least one comorbid condition (77%), and almost half (48%) were retired. A greater number (72%) reported experiencing at least some or even great improvement since they started taking the supplement. Statistical analysis indicated a significant difference (p<0.0001) in distributions of quality of life responses when comparing responses before and after taking the product. Multivariate analysis indicated that the duration of administration (p<0.0001), employment (p<0.012), comorbidity (p<0.012), and GFR (p<0.0015) were significant factors influencing the reported quality of life. Even the disabled respondents all reported significant improvement of probiotic bacteria.

METHODS

Survey questionnaires along with stamped and addressed return envelopes were mailed out to 951 current repeat customers of Renadyl[™]. Out of 951, 117 were excluded due to mailing errors and other reasons, with the final sample size of n=834. Results were tabulated and analyzed using SAS V9.2 and MS Excel software tools.

RESULTS

Gender	N(%)
Female	71 (42%)
Male	79 (47%)
No answer	18 (11%)
Age (years)	
<51	17 (10%)
51-60	22 (13%)
61-70	56 (33%)
71-80	36 (21%)
81-90	24 (14%)
91>	5 (3%)
No answer	8 (5%)

	No answer	6 (4%)	No answer	23 (14%)	
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5 (<15)

19 (11%)

Current wellness

12 (7%)

Wellness at diagnosis

81>

Medical conditions		Comorbidities (Conditions 1-6)		Other conditions	
1-Diabetes	43 (26%)	None	39 (23%)	Autoimmune	5 (3%)
2-Hypertension	98 (58%)	1	65 (39%)	Arthritis	4 (2%)
3-Heart Disease	35 (21%)	2	38 (23%)	COPD/asthma	4 (2%)
4-Obesity	22 (13%)	3	19 (11%)	Hypothyroidism	4 (2%)
5-Cancer	13 (8%)	4	5 (3%)	Gout	3 (2%)
6-Gastrointestinal	18 (11%)	5	2 (1%)	Osteoporosis	3 (2%)
None of the above	23 (14%)			Others	<2% ea.
No answer	16 (9.5%)				

CONCLUSIONS

Based on the customer survey and the results from our randomized clinical trials, Kibow's product-Renadyl™ is well documented to provide benefit to patients in all stages of CKD and with a variety of comorbid conditions. It does not interfere with any other medical treatments, including dialysis. It appears to have a stabilizing effect on the overall health status and quality of life, maintaining or improving kidney health in particular. Further, adequately powered studies that could establish a clearer correlation between this supplement and its impact on GFR are warranted.

Excellent	12 (7%)	Excellent	18 (11%)
Very Good	34 (20%)	Very Good	53 (31.5%)
Good	47 (28%)	Good	70 (42%)
Fair	25 (15%)	Fair	26 (15.5%)
Poor	26 (15.4%)	Poor	0 (0%)
Very poor	16 (9.5%)	Very poor	0(0%)
No answer/NA	8 (5%)	No answer	1(1%)

REFERENCES

http://www.kibowbiotech.com/journal-publications/