

Impact of Gut Microbiome on Quality of Life in Customers with CKD using RenadylTM: Results of a Survey



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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 the gut-brain axis in autism and anxiety. 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 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 survey study aimed to collect information about the impact of gut microbiome modulation with Renadyl™, a probiotic dietary supplement for kidney health, on quality of life and health status of current customers with CKD using this product.

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%) |

| Employment | N(%) |
|---------------|----------|
| Employment | · · · |
| Employed | 31 (18%) |
| Self-employed | 20 (12%) |
| Unemployed | 8 (5%) |
| Disabled | 9 (5%) |
| Retired | 80 (48%) |
| No answer | 20 (12%) |

| Age at CKD diagnosis (years) | | CKD Stage (GFR) | At start of Renadyl |
|------------------------------|----------|-----------------|------------------------|
| <18 | 7 (4%) | No CKD | 6 (4%) |
| 19-40 | 24 (14%) | 1 (90> mL/min) | 9 (5%) |
| 41-50 | 13 (7%) | 2 (60-89) | 9 (5%) |
| 51-60 | 32 (19%) | 3A (45-59) | 27 (16%) |
| 61-70 | 51 (30%) | 3B (30-44) | 29 (17%) |
| 71-80 | 23 (14%) | 4 (15-29) | 46 (27%) |
| 81> | 12 (7%) | 5 (<15) | 19 (11%) |
| No answer | 6 (4%) | No answer | 23 (14%) |

| Medical condit | ions | 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%) | | | | |

Results... contd

| Wellness at diagnosis | | Current wellness | | |
|-----------------------|------------|------------------|------------|--|
| 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%) | |

| Impact of Renadyl | | |
|-------------------|------------|--|
| Great improvement | 39 (23%) | |
| Some improvement | 63 (37.5%) | |
| Neutral | 47 (28%) | |
| No improvement | 8 (5%) | |
| No answer | 11 (6.5%) | |

| Variable | p value |
|----------------------------|---------|
| Duration of taking Renadyl | <0.0001 |
| Emplyed/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 (61%) 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.

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.