

Environmental Heat Stress or Toxins: Why Are We Waiting to Explore Treatment Options for CKDu?

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Editorial

In the ten years since the publication of the article "Poisoned Land" by Elif Batuman in the New Yorker [1], the scientific community and the public have debated the cause of Chronic Kidney Disease of Unknown Etiology (CKDu). Is CKDu caused by heat stress, environmental toxins, or a combination?

However, while much attention has been given to possible causes of CKDu for the past decade or more, nobody has explored potential treatments beyond traditional dialysis. As is evident from a recently published article from Fletcher Reveley, published in Undark Magazine [2] and the 2013 New Yorker article mentioned above [1], many farmers and laborers in agricultural communities in countries like Sri Lanka and India, as well as throughout the Balkans and Mesoamerica, have been diagnosed with CKD (Figure 1). These workers are subjected to extremely harsh working conditions, such as high temperatures for long hours and exposure to environmental toxins like pesticides and herbicides. As a result, many workers have died of kidney failure and will continue to die under these circumstances, with several thousand young lives lost every year to this illness.

Our primary goal is to investigate and explore a potential new treatment for CKDu and to help improve life expectancy and quality of life for poor laborers in the affected countries. For the past 25 years, Kibow has been actively researching and using pre/probiotics to remove various uremic toxins from the body and thus slow the progression of CKD. Our patented Enteric/Intestinal Dialysis technology utilizes highly specialized and carefully selected strains of probiotics, which populate the gut and metabolize uremic toxins such as urea, creatinine, and uric acid. This kidney health dietary supplement, marketed under the name Renadyl™ [3], has been available since April 2010 with no adverse effects reported to our company or US-FDA.

Another Enteric/Intestinal Dialysis component is the prebiotic (fiber), marketed as Kibow Fortis® in the United States [4]. This multi-functional multi-fiber product was specifically developed to improve the efficacy of the probiotic Renadyl™. Kibow Fortis® works to strengthen gut barrier integrity by promoting the production of short-chain fatty acids (SCFAs). SCFAs are an essential fuel for all mitochondria in cells throughout the body; therefore, they can improve the overall quality of life in patients with CKD. All of this is related to arresting the decline of kidney function (eGFR). Additionally, both Renadyl™ and Kibow Fortis® have been shown to be lactogenic and bifidogenic, encouraging the growth of beneficial microbes, especially bacterial probiotic strains of genus *Lactobacillus* and *Bifidobacterium*.

The primary pathway for these products is to decrease the production of

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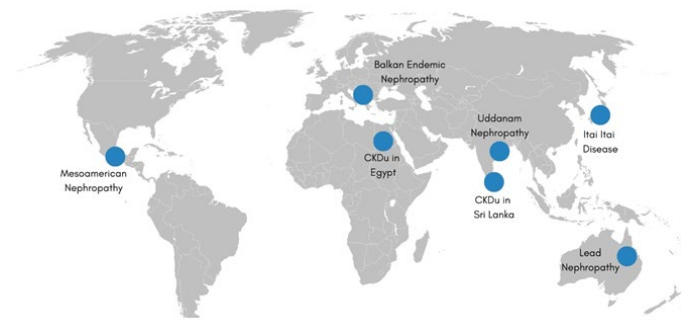


Figure 1. CKDu hotspots around the world.

pathogenic bacteria and the modulation of the gut microbiome. The dream of using Enteric/Intestinal Dialysis with pre- and probiotics to slow the progression of CKD and delay the need for conventional dialysis has become a reality [5].

While both products are sold as health supplements, our 25 years of research and development capabilities have been based on a pharma-like validation process. The company is conducting phase 2B clinical studies on a slightly modified (cardiorenal-targeted) formulation involving 630 patients with CKD Stage 4. The author of this editorial, principal founder of Kibow Biotech and chief architect of enteric dialysis technology, has spent decades researching applications for this technology in patients with CKD. His only question is: If this technology is suitable for CKD patients, would it not also work for CKDu? Therefore, Dr. Ranganathan proposes worldwide researchers perform open-label clinical studies based on Enteric/Intestinal Dialysis technology, to determine its suitability for patients with CKDu, in the interest of helping improve the quality of life for poor laborers whose situations are often overlooked all these years.

To this end, Dr. Ranganathan has recently established his own privately funded philanthropic foundation, "Dr. Rangan and Pari CKDu Foundation," which seeks to fund research into novel treatments for CKDu. So, why are we waiting? First, let us all team together to jumpstart the new area of CKDu treatments. Dr. Rangan proposes conducting an open-label pilot-scale observational study of 10 healthy, 20 CKD, and 40 CKDu patients affected from the same location. The protocol for this clinical trial is currently under review and will be published soon. For further information, please contact Natarajan Ranganathan (Dr. Rangan), the founder and gut microbiome lead scientist of Kibow Biotech, at Rangan@kibowbiotech.com.

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