The Wearable Artificial Kidney

This month, Kidney News interviews Victor Gura, MD, developer of the wearable artificial kidney.

Victor Gura, MD

KN:  Please tell us something about yourself.

Victor Gura: I was born and raised in Buenos Aires, Argentina, and graduated from the National University of Buenos Aires Medical School. There was a lot of turmoil in Argentina in those days, so I decided to leave. I went to Israel, where I did my internship, residency, and renal fellowship. Then I came to the United States and did a second renal fellowship. I then worked in private practice until I decided to get back into research and develop the wearable artificial kidney (WAK). Currently I devote a major part of my time to this endeavor.

KN:  How did you come up with the idea of the WAK?

Victor Gura: The outcomes of long-term dialysis treatment were disappointing—and remain so to this day. The poor quality of life, premature mortality, and plight of patients with ESRD drove me to look for a better way to treat them. In the late 1990s, there was a mounting body of literature praising the many benefits of daily dialysis: less morbidity, better quality of life, and potentially less premature mortality.

It became obvious that longer treatment time is crucial and that unless we could do much longer and more frequent treatments, clinical outcomes were unlikely to improve. On the other hand, daily dialysis or dialysis for longer sessions remains impractical for the vast majority of ESRD patients. I could not implement daily dialysis for most of my patients because it would cost money we did not have, there was no way we could double the number of dialysis chairs available, there were not enough nurses, and patients in general are loath to spend more time tethered to a machine.

KN:  How long have you been working on the WAK since you first conceptualized it?

Victor Gura: I started this project in the summer of 2001.

KN:  Please differentiate the WAK from current modes of renal replacement therapy.

Victor Gura: The WAK is designed to be worn on the patient’s body so that it provides continuous renal replacement 24/7. In its current version it weighs about 11 pounds, but it delivers 168 hours per week of blood filtration, just as the native kidneys do, instead of filtering the blood for only 9 to 12 hours a week, as is done today. Because it works on batteries and requires only about 400 mL of water, it does not require a hookup to an electrical outlet, nor does it require about 40 gallons of fresh water, as current machines do. Because of the small amount of water required, the use of intravenous-quality sterile water is then feasible and affordable. This water quality is superior to the quality of ultrapure dialysate used in Europe and far better than the quality of water used in the United States.

Ultrafiltration at physiologic rates of fluid removal would virtually eliminate the hemodynamic problems we so often see in patients requiring removal of large amounts of fluids in a short time. Inasmuch as the WAK also maintains adequate homeostasis of electrolytes while removing excess salt and phosphorus, we expect to liberalize diet and fluid intake and reduce the “pill burden” on patients. We hope to demonstrate that the WAK will improve the outcomes of long-term dialysis in terms of quality of life, mortality, and costs.

KN:  What obstacles and challenges have you encountered since you started working on it?

Victor Gura: Lack of funding was and remains the main obstacle. When the project started, I encountered a lot of contempt and disbelief. Many thought I was a lunatic Don Quixote, taking on the windmills. The WAK was then the subject of a few jokes, a lot of cynicism, and lack of support from traditional funding sources. Since then we have gained a lot more credibility. However, there is no support from the dialysis industry. We have had no venture capital support even after winning the US Food and Drug Administration (FDA) Innovation 2.0 Award.

KN:  What was your experience with animal studies?

Victor Gura: Initially I wanted to do an animal trial on dogs because of my previous experience with uremic models in this species. However, this idea was rejected by the Institutional Review Board for Animal Use. They feared problems with groups that oppose experimentation with animals and said that if we used pigs instead, there would be less opposition. The uremic animal model in pigs was not described in the literature, so we had to create one. We encountered some surprises: we discovered that pigs become very uremic and hypertensive immediately after the ureters are ligated. We also found out that pigs require a much higher dose of heparin related to body weight in comparison with humans of similar body weight.

KN:  What was your experience with the first human clinical trial and experience?

Victor Gura: As we concluded the pig study in Los Angeles, Claudio Ronco showed up in my laboratory and told me that he had heard from my late friend Hans Dietrich Polackseggh that we had a working WAK model. Claudio was bold enough to believe in this project, so he invited my team to work in Italy.

We did the first human trial at San Bortolo Hospital in Vicenza, Italy, in collaboration with Ronco’s team. We treated 6 patients with the WAK configured for ultrafiltration only for up to 6 hours, with no adverse effects. The device worked as expected. As this work was published, Andrew Davenport of the University College London Center for Nephrology, Royal Free Hospital, offered to do in London a second human trial but this time with the WAK fully configured for hemodialysis. We treated 8 patients for up to 8 hours with no adverse effects. The data from this trial also indicated that the device does in fact work as expected. We are using the same prototype in our first human trial in the United States for up to 24 hours in Seattle, Washington, in collaboration with Jonathan Himmelfarb and his team. In both studies we used a most rudimentary prototype, which needs a lot of improvement, and we will have to develop and miniaturize the WAK further before we launch the next human trial.

KN:  What made you persevere in pursuing the WAK?

Victor Gura: My first thought is that I am stubborn. I think that my wife would agree with that. But to be serious, I have a profound belief that this is the right thing to do, and I have a strong commitment to persevere and get the project completed. I think that as nephrologists we have an obligation to innovate, and we owe that to dialysis patients.

It seems to me that as a nephrology community of physicians, academics, and industry, we have failed for decades to innovate in this field, and we have become complacent. We have done little to bring to bear on the technology of dialysis equipment the enormous progress achieved in other technology fields for the past 6 decades since Kolf invented the dialysis machine. All kinds of technologies around us have become miniaturized, but no one has done enough to miniaturize the WAK. The plight of patients with ESRD must be alleviated, and we need to be creative enough to make that happen. I believe in what I am doing, and I will continue to work very hard to prove it. I was lucky enough to be guided by a wonderful group of mentors and colleagues, and I am very lucky to be supported by my wonderful wife and friend.

KN:  Please tell us what is the latest news with the WAK.

Victor Gura: The first human trial has been completed. It seems that we will have a large amount of data to contribute to the field of innovative technology for ESRD. That data must undergo peer review before it is divulged to the public. As such, we will first announce these data in a peer-reviewed scientific forum and publish the study in a peer-reviewed journal.

KN:  How do you see the future of WAKs?

Victor Gura: The WAK will undergo considerable improvements based on the lessons learned in our latest trial. We know much more now about what works in the WAK and what needs improvement. There is a lot to do, but based on what we already know, we hope to bring about a better alternative for the treatment of ESRD. Although it is too early to predict which patients will choose the WAK, we are inundated with patients’ requests from around the world to use the WAK.

KN:  What do you think about its applicability to patients in underdeveloped countries?

Victor Gura: The world cannot afford dialysis for all those who need it. We must reduce the cost of dialysis and make it more affordable to underserved populations around the globe. Underdeveloped countries are in dire need of affordable dialysis. Also, by reducing the morbidity associated with ESRD, we may decrease the economic burden of kidney failure. We hope that ESRD patients will require fewer procedures and fewer drugs and will go to the hospital.
much less often. We have not yet met those needs for more affordable and better technologies, but it is abundantly clear that many people in underdeveloped countries perish because no dialysis is available or there is no money to pay for dialysis.

**KN: Tell us about the WAK foundation: http://wakfund.org/**.

**Victor Gura:** The WAK foundation is a 501(c3) public charity established for the purpose of funding WAK research in academic centers of excellence around the country with the hope of accelerating the development of the WAK and making it available to patients as soon as possible. The officers of the foundation are kidney patients. The first trial in the United States, conducted in Seattle, was funded by charitable gifts.

**KN: Are there ongoing trials in other countries?**

**Victor Gura:** Not at the present time. The FDA and our team have agreed to carry out our clinical trials in the United States only. This was a requirement of the FDA Innovation 2.0 competition.

**KN: If you had an opportunity to turn back the hands of time, what would you change? Or not change?**

**Victor Gura:** Change? I would be much more cautious about accepting investments from business people who attempt to take control of a project in a field where they have no previous experience. I would not become a public entity again by reverse merger. That was a major mistake. Not change? I would pick my associates very carefully, and be fiercely loyal to those who do the actual work and support the project. I would accept setbacks as opportunities to learn and improve.

**KN: What would you advise younger colleagues as they learn from your experiences?**

**Victor Gura:** Be mindful of the company you keep, because you are only as good as the co-workers you associate with. Don’t be afraid to come up with good ideas. If you decide to innovate in your field, make sure that you identify an unmet need, develop a plan to answer such a need with a solution, and be prepared to work very hard to make it happen. If you believe in what you do, do not allow disbelief and contempt to prevent you from doing what you believe is right. One of my favorite quotes is this: “Those who say it can’t be done are usually interrupted by those doing it.”

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- Geriatric Nephrology: Caring for Older Adults with Kidney Disease
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