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The Wearable Haemodialysis Device for ESRD

VARIABLE HEMODIALYSIS, A PROMISE OF PORTABILITY

You are listening to ReachMD XM 157, the channel for medical professionals. Welcome to clinician's roundtable.

I am your host Dr. Gary Kohn and joining me is Dr. Victor Gura. Dr. Gura is associate clinical professor of medicine at the UCLA, David Geffen School of Medicine. He is also an attending physician at the Cedar Sinai Medical Center.

Today, we are going to be discussing a variable hemodialysis device and it is used in end-stage renal failure.

DR. KOHN:

Dr. Gura, welcome to ReachMD. Thanks for taking some time to be with us today.

DR. GURA:

You are very welcome sir.

DR. KOHN:

Before we get into this topic, could you tell us a little bit about your own medical background and what led you into this particular area of research.

DR. GURA:

Well, I went to medical school in Buenos Aires, Argentina. My father was a physician. I did my internship in residency in Israel, Tel Aviv University Medical School. I was in this service in Israel for 11 years in the medical court of the air force in the army. I was flight surgeon. I also did my residency and nephrology training in Israel. I did an additional fellowship here at USC, University of Southern California, and then I started to practice medicine doing dialysis, nephrology, which is my area of specialty at Cedar Sinai and in this area and I also started to be involved in the teaching nephrology and internal medicine as a clinical faculty at UCLA.

DR. KOHN:

This idea of hemodialysis and portable hemodialysis fits in nicely with your life's work, obviously, but let me ask you that before you and your team publish in Lancet before that, had any work been done on portable hemodialysis devices.

DR. GURA:

Oh, yeah.

DR. KOHN:

Could you tell us what was the state of the art?

DR. GURA:

Dialysis and portability has been sort of the Holy Grail of the world of nephrology for decade. A portable dialysis was done by William Cole, who was a giant in our field and also is the Father Of Modern dialysis and he tried to develop the variable that never went anywhere in terms of commercialization, but he actually built one. It was rather heavy and could not go around for more than a couple of hours. Later on, Dr. Eli Friedman developed a dialysis device that went in a suitcase and was portable. Also, Dr. <_____> in waring Korea used some sort of portable mobile dialysis device in the field and there have been others that attempted to build a dialysis machine that was portable and, portable can mean that you can put it in the trunk of your car and move it or you can wheel it from one room to the next, but the concept of wearability as opposed to portability is a different concept. There were very important reasons that became apparent in the late 90s, early 2000 of why wearable was important. Wearable is important because as it is something that ergonomically adapts to the contour of the body and its independent from an electrical cord because it is battery operated and instead of using 120 liters of fresh water for treatment, uses only 375 cc of fluid that is constantly regenerated, then you can become truly wearable and create something that is near to arrive and people can wear it 24x7.

DR. KOHN:

Well, that would be quite a bit different than they experience today. Could you tell us a little bit about the actual unit that was used in this pilot study, size, weight, patient experience, can you help us picture it?

DR. GURA:

Yes, definitely. The wearable artificial kidney built today shown in the last paper in Lancet, although there are other papers describing the wearable artificial kidney and kidney international contributions to nephrology and the <_____> journal is based on the fact that it is adapted to the contour of the body as a belt. It is operated on batteries that they are very light. The particular study we showed in London used 9 volt batteries. The weight of the device, which <_____> in the London study weighed about 10 pounds and people could walk around with it, but the crucial thing is that we can really impact outcomes. We nephrologists have been a little arrogant over the decades, thinking that if we dialyze somebody 3 or 4 hours 3 times a week, we can actually replace the kidneys and we never got up until recently with the fact that our native kidneys work 24 hours x7, so thinking back what would make us believe that 12 hours of filtrating blood is as good as 168 hours of filtering blood every week and it simply does not make any sense when you put it that way.

DR. KOHN:

But it was the best we could do, we thought.

DR. GURA:

We thought and in the 80s, we tried to reduce the dialysis time from usually 4 hours to 2 hours with the use of highly efficient High Flex dialysis machines and filters and the mortality increased so much so that people went quickly back to 3 and 4 hours because then the mortality came back to what it used to be before. Yet, the mortality and morbidity of patients on dialysis is unacceptable. The mortality is equal to the mortality of patients with metastatic cancer of the breast or the colon.

DR. KOHN:

That is not good; I take it from your earlier discussion that a good part of that is because of the lack of dialysis time.

DR. GURA:

Correct and today, there are 100s of papers mounting evidence in the literature, pointing to the fact that we should dialyze every day; you can radically alter the outcomes of chronic dialysis.

DR. KOHN:

If you are just joining us, you are listening to clinician's roundtable on ReachMD XM 157, the channel for medical professionals. I am your host, Dr. Gary Kohn and I am speaking with Dr. Victor Gura and we are talking about a wearable hemodialysis device.

Victor, you were telling us a little bit about the actual device that was used in the pilot study, what was the patient experienced, can we feedback on how they did with it?

DR. GURA:

The patients loved it. There was not 1 complaint. The only thing they said that was not positive as well, we would like it to be a little less obtrusive, so we can move around without everybody looking at that, but the bottom line is we put those devices in London on patients above their clothes as opposed to under the clothes because we were closely observing the device and its performance. The device is intended to be worn on the skin, under the shirt, under the skirt, and people could walk around, go to work, and travel while undergoing dialysis 24x7.

DR. KOHN:

How does the fistula needle work in patient, who is continually ambulatory, any problems there?

DR. GURA:

Well, there is no fistula needle. This works exclusively with a catheter. You can't have 2 large borne needles on the arm of the patient held by some flimsy pieces of tape and have the patient walking around and getting in a bath or going to work, it's dangerous. So, the wearable artificial kidney is intended for being used only with the central catheter, which we have designed.

DR. KOHN:

What were your findings with respect to electrolytes, acid base balance, that sort of thing?

DR. GURA:

There were no problems whatsoever with acid base with electrolyte balance and we also removed effectively all the fluid we wanted to remove, but that the most important thing is that fluid should be removed from the body in a slow and steady fashion, as opposed to trying to remove 3 or 4 liters every 2 days in 3 or 4 hours. That is very unphysiological and is no wonder patients feel sick the day after dialysis. With this device, there was not 1 complaint, no nausea, no vomiting, no dizziness, no diarrhea, no cough, and no nothing.

DR. KOHN:

Your pilot study showed that this is obviously promising for the future, both in terms of patient acceptable as well as clinical criteria, what is next in your research?

DR. GURA:

Well, first of all, the most important thing is we believe that this should be the new standard of care 1 day and the reason is that we believe this is the way to provide people with daily dialysis without having to build new dialysis unit, getting nurses we don't know where to find and finding the money to do it. So, this is 1 of the crucial issues. In terms of the next steps, we are going to proceed with further clinical trials in an iterative form that is we did 8 patients for 8 hours. Now, we are going to go into 24 hours, 48 hours, a week, a month, 3 months and hopefully after those studies, the FDA will allow us to go to market.

DR. KOHN:

At this point then, what is the take home message to physicians who have patients on hemodialysis, is this something that is going to happen in the next decade, do you think?

DR. GURA:

I would hope and desired as to have it tomorrow in the market, but we believe in a couple of years, we will have it out, but I cannot promise that, but my take home message to doctors that have patients on dialysis, dialyze frequently, dialyze long, and your patients will live longer.

DR. KOHN:

Let me ask you this again, I know you can't predict future, but how do you think in terms of cost, this unit will compare in the process, will compare with our current hemodialysis regimens?

DR. GURA:

Well, here is the situation. Medicare has spent about 30 billion dollars a year in keeping the dialysis population alive and about one-third of this goes to pay for hospitalizations, drugs, surgeries, their data upon data that on daily dialysis, those 10 billion dollars can be sliced out. So, that is savings #1. These are not our data. These are data from the folks that have been doing daily dialysis, anybody that has any interest confined to papers, on how daily dialysis saves so much money. In terms of the cost of our device, we cannot give at the present time any firm data, but we believe that the cost of keeping somebody on dialysis 24x7 for a month is going to be similar to the cost of keeping somebody alive with 3 times a week for 4 hours.

DR. KOHN:

Oh! That is impressive. Let me ask you this. What do your more traditionally minded colleagues think about this direction of research when your paper came out, what kind of feedback did you get?

DR. GURA:

Well, I have been working on this since 2001. At the beginning was skepticism, then is an attitude of well you know, lets see if you can really deliver. Right now, people are very enthusiastic, no matter where I go in the world to talk about this, there is a great hope and we will do our biggest efforts not to disappoint the community and the patient, but everybody had to wait and see the atitude, now, everybody is beginning to buy into the concept.

DR. KOHN:

Is the next generation of docs going to be thinking differently about hemodialysis you think?

DR. GURA:

Well, there are plenty of things that happen everyday that makes the young generation see new things happening everyday. The advances are enormous in so many fields. So, they are very open, the young guys are open to everything new, it is astonishing. The more conservative falls that have been around for 20 to 30 years that more or well, lets see because this has been tried before, how come you did it and other people didn't.

DR. KOHN:

All right. Well, I think it is fascinating as well and I hope to hear more from your group and I hope to hear more on the process itself since

like our patients will benefit. I want to thank Dr. Victor Gura for being our guest.

We have been discussing a pilot study for a portable hemodialysis device. I am Dr. Gary Kohn and you have been listening to clinician's roundtable on ReachMD XM 157, the channel for medical professionals. To comment or listen to our full library of Podcasts, visit our site reachmd.com. Register with promo called radio and receive 6 months free streaming to your home or office. Thanks for listening.