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Key Insights on Early Management of Diabetic Kidney Disease

Announcer:
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This medical industry feature, titled "Key Insights on Early Management of Diabetic Kidney Disease" is sponsored by Renalytix. This program is intended for physicians.

Here's your host, Dr. Charles Turck.

Dr. Turck:
Chronic kidney disease in type 2 diabetes, also known as diabetic kidney disease, is a growing health epidemic, and the tools clinicians currently use to detect it may not provide the full picture of kidney health, but an emerging prognostic tool may change that.

This is ReachMD, and I'm Dr. Charles Turck. Joining me to take a look at a prognostic tool for diabetic kidney disease care is Dr. Michael Donovan, who is the Chief Medical Officer of Renalytix. Dr. Donovan, welcome to the program.

Dr. Donovan:
Thank you very much. Nice to be here.

Dr. Turck:
To start us off, Dr. Donovan, can you give us an overview of diabetic kidney disease? What do we need to know about the burden and progression of this disease?

Dr. Donovan:
So, I think it's important to understand that diabetic and chronic kidney disease, as it's known, more colloquially, is a really a systemic issue that is, I think a call to action with respect to its, ability to impact on the population. There's about 37 million adult patients in the United States with chronic kidney disease, which is in itself, is an epidemic of really unknown proportions with regards to the impact that this disease would have on the population in general, and this represents, and is initiated predominantly by, diabetes as well as hypertension, so two very prevalent diseases throughout the adult population, and so you can see that translates to the 37-38 million folks that have chronic kidney disease in the adult population today in the United States. And about 95 percent of those patients are in the early stages of chronic kidney disease, so we look at that from stages 1 through 4, and about 5 percent are in late-stage disease. So, the impact is quite significant in a population that is, in itself, really morbid with regards to the overall and eventual outcomes, but in the numbers of patients and the distribution of that population is quite significant.

Another point that's very important to understand is of that 38 million patients approximately that we have with adults with CKD, they're being managed today by their primary care physicians predominantly. There are only about 8,000 nephrologists in the United States and about 7,000 endocrinologists, so small numbers to be managing those patients. So, you can see the majority of the adults with chronic kidney disease are being seen and managed by their primary care physicians, which is about 210,000 across the United States. So, that ability to be able to manage those patients with all of their systemic diseases is rather challenging, and that's why we focused really on identifying a tool that would be able to parse out those patients, to identify those with high risk for progression of their kidney disease, and to really assist the primary care physician in terms of the effective management of those patients.

Dr. Turck:
And how can we determine which of our patients with diabetic kidney disease are at risk of progressing earlier?

Dr. Donovan:
So, that's a very good question, because I think today, there are clinical variables that are used, in the clinical laboratory setting, eGFR, which is an estimated glomerular filtration rate, as well as a protein within the urine, which is a test known as uACR, which is looking at albumin levels as well as creatinine levels within the urine. And those are the two elements that are used to assess overall kidney function, and unfortunately there's a lot of variability and heterogeneity with respect to those individual markers and how they're actually used. So, the idea was to refocus from the primary care perspective as well as the tools that are available, and that's why we developed a test that was a tool that could measure elements within the blood as well as additional clinical variables, including the eGFR and the uACR, but also other tools that can help to define and really refine that phenotype of a patient that is most likely to progress.

Dr. Turck:
Now let's talk about one tool in particular—KidneyIntelX. How does this tool work?

Dr. Donovan:
So, KidneyIntelX is a relatively straightforward device tool, which we call it is a bioprognostic. And what that means is that it utilizes blood from the patient, which is then used as part of this bioprognostic test with measurements taken on specific markers within the blood. And those measurements of specific markers are the TNFR1, TNFR2, and KIM-1, which is looking at immunologic-based markers, which the TNFR1 stands for tumor necrosis factor 1, tumor necrosis factor 2, and then KIM-1, which is the kidney injury molecule. And those are the biomarkers that we are measuring with context of this device and then combining those through an algorithm that actually weighs differential clinical features, such as calcium and liver function tests and blood pressure and hemoglobin A1C, which is a reflection of their diabetes, as well as platelets. And those individual markers in the context of the biomarkers that are present within the blood are quantitatively measured and then differentially weighted with respect to the generation of a risk score. And that risk score predicts the likelihood of a progression of declining kidney function, which is based on specific three endpoints in the context of this model. And the three endpoints we're looking at a change in the eGFR slope, so that's prediction of a future event with respect to kidney outcome and estimated glomerular filtration function, or actual kidney function, as well as a decline of a 40 percent sustained decline in that eGFR over a period of time as well as end-stage renal disease. And the test utilizes the biomarkers plus the clinical features at that baseline level, and based on the validation studies, have been able to effectively predict the likelihood of an individual patient with the measures of those biomarkers and their clinical features, are most likely to progress their disease. And so, it's a way to identify and distribute a specific risk level for individual patients.

So, the test report generates from that blood measuring those three biomarkers with clinical data a risk score, which is associated with the level of risk, so low, intermediate, or high risk, and on the report itself, there are specific ways in which those levels of risk can be interjected into existing guidelines, and that's something that we believe strongly of in terms of utilizing what is available out there from the American Diabetes Association as well as some of the kidney networks that actually have established a kidney, a KDIGO heat map, if you will, which takes those measures that I mentioned, of eGFR and uACR, as a way to identify a stage of disease for an individual patient.

Dr. Turck:
For those just tuning in, you're listening to ReachMD. I'm Dr. Charles Turck, and today I'm speaking with Dr. Michael Donovan about the early management of chronic kidney disease for patients with type 2 diabetes.

Dr. Donovan, let's dive deeper into KidneyIntelX. How does this tool differ from existing tools for identifying patients at high risks for kidney disease?

Dr. Donovan:
So, this tool is different from pretty much any other test that is out there because of that utilization of biomarkers that are present within the blood for an individual patient. It actually measures those in the context of their clinical data and derives a risk score based on an outcome, that composite outcome that I mentioned.

Other tools, there are algorithms that are available online through various channels that utilize existing parameters, such as eGFR and uACR. But they're done for end-stage disease. They've not been validated within the context of early-stage disease, and that's a real differentiator, both from a personalized medicine perspective of biomarkers of the patient's own blood and to derive elements of understanding of their kidney health, and then combining that with clinical features of that patient to be able to generate a risk score versus what is currently available are clinical algorithms, which are population-based, derived really, and focused on end-stage kidney disease, but don't really get at the patient in front of you and how you'll actually evaluate that individual patient.

Dr. Turck:
Have any clinical data emerged supporting the use of KidneyIntelX?

Dr. Donovan:
So, this has been, obviously, quite a number of published studies that we've done through this process from the clinical validation studies, which are available on our website and accessible, and most recently was in the *Diabetologia*, which is the second validation study on the KidneyIntelX assay. And then subsequent ones that actually built upon that message of understanding of the impact of these biological markers that we're measuring within blood and how they can be adjusted and changed with respect to various novel therapeutics that have a way to adjust to that level of disease within the kidney and a reflection of kidney health.

We've also generated a significant amount of data on the use of these tests in clinical practice; there's a real-world evidence study that is utilizing the test across a number of practices and physicians' networks throughout the Mount Sinai Healthcare System, and it does that in a way to look at the decision that physicians make with regards to the level of risk.

And we did present a poster at the late-breaking session at the ADA meetings this past June that demonstrated the impact that a risk score such as the KidneyIntelX has in the context of this disease, which is obviously a complex scenario because it's a systemic disease. Physicians were utilizing that level of risk to actually modify their treatment plans, and that, to me, tells you that there is a need with respect to the clinical space, and now there's a tool that can actually help to refine that thought process and drive forward with ways to bring in consult services, to bring in nephrology, endocrinology, diabetology, as well as nutrition and ways to support the social network that these patients need with regards to their current state of their disease, as well as pharmacy to drive forward some of the novel therapies that are currently available.

Kidney disease itself, including its link to cardiovascular disease, has benefited from a number of novel therapeutics that have come forward – SGLT2 inhibitors, GLP-1s, MRAs – that have all really changed the practice of managing these patients more effectively. The challenge obviously is that we need ways to be able to identify those patients that are at higher risk because through our validation studies and continued efforts to understand what percentage of population at high risk is, it varies from 12 to 15 percent. So, you're looking at a smaller percentage of patients that have a high chance of moving forward with the progression of their disease, but how do you identify those patients most effectively? And this is a tool that helps to really refine that approach and identify those appropriate patients. And that's what's coming out from these real-world evidence studies as well, that not only are they introducing consult services and specialty services, but they're also utilizing some of these novel therapies as well as modifying some of the existing therapies that these patients are on.

And then getting to the high-risk level of patients where you really need to do something much more urgently with regards to the management side because the likelihood of progression of disease within the high-risk group is 15 times based on what we're seeing in our studies and our validation networks that are driving that understanding of the risk is quite significant, and you really need to do something about this with this individual patient, and that means bringing in some of these services. That supportive measure drives forward through a lot of the discussion that the provider has with the patient, and that is something that comes out in many of our discussions with the primary care physicians that are actually utilizing the test in practice, and what does that mean for them with regards to that discussion, engagement, and modification of treatment, which I think is very telling for what these kinds of tools can actually provide.

Dr. Turck:
Before we close, Dr. Donovan, can you share some of the biggest takeaways for physicians who want to improve their patients' kidney health?

Dr. Donovan:
So, I think for me and for physicians, I try to convey that there is a need here with regards to taking your current management approach towards individuals with hypertensive disease or with diabetes is to really take a hard look at the kidneys in that context and go outside of what your comfort zone has been and really look at ways in which that can be addressed, and I think that's why tools like the KidneyIntelX that measure specific biologic immune markers within the blood that are a true reflection of kidney disease at the glomerular level and at the tubular level, that level of risk and introducing those kinds of bioprognostic tools in that management approach is very important to do.

And I think the other message is to utilize the guidelines that are out there and the care path mechanisms that are in place to really investigate some of the novel therapies that are available because it does impact on overall survival in the cardiovascular setting, which is directly linked to the kidney, and so these are health issues that I think need to have a refocus with regards to the population that is managing these patients because it's at another level now, and I think we need to really make sure that those are kinds of activities that are introduced.

And I think the third piece that's to me is so important is how to really look at your engagement with the individual patients that you're managing and what to do to drive forward with some of that messaging that's so important, and we really understand the limits with

regards to the time from a patient-provider engagement level, especially at the primary care setting, is so challenging, and messaging-wise is so critical, and I think that becomes an important understanding of level of engagement, and anything that helps to shine that light and let the patient understand that they have kidney disease, and this is a time to actually change some of their behavior and some of their compliance approaches.

I'm hoping that we'll actually shed some light on what is a very significant health issue that needs to be addressed.

Dr. Turck:
That's a great comment for us to think on as we come to the end of today's program. I want to thank my guest, Dr. Michael Donovan, for helping us better understand the tools used to manage chronic kidney disease for patients with type 2 diabetes. Dr. Donovan, it was great speaking with you today.

Dr. Donovan:
Thank you very much.

Announcer:
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