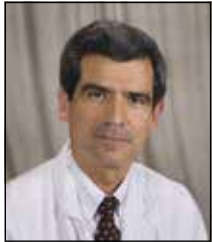


Cardiology tech innovations surge thanks to Big Data, Early Precision QT, other advancements

By CAURIE PUTNAM

When it comes to technological and digital advances in cardiovascular care, “We’re in a rapidly changing time,” according to Dr. Spencer Rosero, the University of Rochester Medical Center’s interim chief of cardiology and director of the Clinical Research Center at the Clinical and Translational Sciences Institute.



Rosero

Rosero, who has been practicing medicine for nearly three decades, notes that the cardiology field seems to experience a jolt of technological innovation every few years and this is

one of those periods.

“Cardiologists have a lot of tools we’ve never had before,” said Rosero, pointing to wearable biosensors, like wrist bands, as one of those tools. “Sensors are everywhere. We have a lot of data and now we’re learning to harness the power of that data to learn from it.”

The medical center has several clinical trials and pilots happening now with wearables and implantable devices that can collect data on measurables including heart rate, breathing, stress level, activity, and sleep and share these important patterns of data almost 24/7 with researchers. Using the predictive health data collected, providers can then tailor treatment and dose modulation of medications in more individualized and holistic ways.

Strong’s innovative Clinical Cardiovascular Research Center includes the Predictive Health Monitoring and Ac-

tivity Core Laboratory (PMAC), which develops predictive health monitoring methods and provides full lab services for the attainment, processing and analysis of data acquired from wearable and implantable sensors in clinical trials.

Rosero notes that due to the medical center’s clinical research, the institution is at the forefront of patient care with wearable and implantable sensors, giving eligible patients access to technological advancements sometimes five to seven years before the general population.

Wearables are also extremely beneficial for patients who may have a challenging time getting to the physical hospital due to economic barriers like transportation or childcare, who live outside of the Rochester region, or are from medically underserved areas with limited access to brick and mortar care. “Digital health is the future of customized care for the individual instead of the group,” Rosero said.

Dr. Jonathan Rodriguez, a cardiologist with Finger Lakes Health’s Geneva General Cardiology Associates, also points to rapid improvements in remote diagnostic tools and telemedicine as an exciting

hallmark of this point in time.

“During COVID we started doing more telemedicine, which has been good for some patients who are limited in mobility,” Rodriguez said. “It’s something good that we have continued to offer. Overall, there’s been more of a focus on remote monitoring, partic-



Rodriguez

ularly for patients with AFib [atrial fibrillation - an irregular heart rhythm] and even patients with heart failure.”

A key player in gathering evidence for clinical trials worldwide is Clario, a company with a strong Rochester connection. ERT, a global clinical endpoint technology company, and Bioclinica, a medical imaging company, merged in 2021 to become Clario. Back in 2017 ERT had purchased iCardiac Technologies, which was founded in Rochester as a company specializing in cardiac and respiratory safety in the clinical trial space.

iCardiac — now a legacy Clario company — developed pioneering algorithm-driven innovations like Early Precision QT, which support efficient, cost-effective and regulatory-compliant methods of conducting QT assessments in early phase clinical trials.

Early Precision QT has been a game changer in collecting and analyzing electrocardiogram data, detecting cardiac safety risks or other concerns early on, and informing drug developers of those findings early in the clinical trial process.

Clario has been involved with over 19,000 clinical trials, helping more than 800 new drugs come to market in therapeutic areas including cardiovascular, dermatology, oncology, and infectious diseases.

The company has 30 facilities in nine countries, including its Rochester office, which houses the company’s cardiac safety statistics team, as well as some data managers and project managers.

“Technologies that can be used at home is the direction things are going right now,” said Dr. Todd Rudo, vice president of cardiology and deputy



Rudo

chief medical officer at Clario, explaining what the technology landscape in clinical trials looks like currently. “Connected devices that can be paired with a smartphone in a

decentralized way are becoming very popular.”

He points to the portfolio of connected devices Clario can offer researchers to assist in the remote collecting and analyzing of data used in decentralized clinical trials. Such clinical trials are often executed through telemedicine, using processes and technologies differing from the traditional clinical trial model where participants would have to travel to a physical site to collect data.

Decentralized clinical trials are important in increasing diversity and equity in clinical research since they can remove or improve barriers to participation, like travel, time commitment and childcare costs.

Devices Clario offers to assist in these types of clinical trials include patch monitors, cuffless blood pressure monitors, and a blood pressure cuff that can be used at home and is much more advanced than an at-home cuff that can be purchased at a store or online. These cuffs have a triplicate inflation feature and collect data more frequently and accurately. They are also paired with a secure smartphone that sends readings to a cloud for researchers to monitor the results and respond appropriately.

Caurie Putnam is a Rochester-area freelance writer.

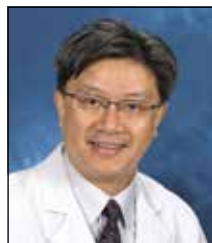
Area experts weigh in on innovative treatments in cardiovascular care

By CAURIE PUTNAM

Despite some setbacks in research and getting people involved in clinical trials over the past few years, this is an exciting time for innovative treatments in cardiovascular care, according to local experts in the field.



Gosev



Huang

From pioneering surgical procedures to new pharmaceuticals for non-invasive treatment of heart issues, the *Rochester Business Journal* talked to three regional health care organizations to learn about the newest treatment trends.

Collaboration and strong teamwork among specialists has led to critical advancements in cardiovascular care over the past several years at the University of Rochester’s Medical Center.

Two of these specialists are cardiac

surgeon Dr. Igor Gosev and electrophysiologist Dr. David Huang. For the past five years, the duo has been using a relatively new hybrid procedure called convergent ablation therapy to treat atrial fibrillation (AFib), the most common heart rhythm disorder.

Symptoms of AFib can run the gamut from none at all to palpitations, dizziness and fatigue. Despite the severity of symptoms, untreated AFib can lead to blood clots and stroke.

Traditionally, AFib patients have been treated with medications, and sometimes ablations — a minimally invasive technique of interrupting the irregular rhythm. Gosev and Huang’s hybrid method takes a pericardioscopic approach and yields exceptional outcomes with low complication rates. It is typically used in the approximate 5 to 10% of patients where standard treatments aren’t enough to control persistent AFib.

Gosev describes the procedure, which focuses on the upper chamber of the heart, as the work of “two very robust specialties coming together to advance patient care.” Huang notes the collaboration offers the region something new and draws patients not only from Rochester but all surrounding major metro-

politan areas.

Patients receiving convergent ablation therapy for AFib tend to be healthier among cardiac care patients as their condition is not typically life-ending, but life-altering when not fully treated. They are typically in their fifties to seventies.

Over the past five years, the Gosev/Huang team has also begun performing a similar collaborative procedure to treat a subgroup of patients with heart failure who have lower chamber heart rhythm issues and are among the sickest of the sick.

Called ventricular ablation and performed less often, this procedure involves the extra step of treating lower chamber heart rhythm issues while performing surgery to place a heart pump. Gosev estimates this combined procedure is done at fewer than 20 hospitals worldwide.

The team at the URMC is leading the definitive clinical trial that investigates the effectiveness of this approach. The team performs 10-15 of these procedures a year, as opposed to about 15-20 of the convergent ablation therapy procedures. They expect both procedures will continue to increase in usage.

“Imparting the skills and the science onto our trainees” is an important aspect of these pioneering cardiac procedures, Huang noted. The University of Rochester is a teaching hospital, and physicians-in-training participate in, and learn from, these surgeries. This approach is part of the Medical Center’s commitment to collaboration to advance patient care.

Collaboration between different health care specialties also plays a major part in cardiac care at Rochester Regional Health, where Dr. Scott C. Feitell, the organization’s director of heart failure says, “Breaking down silos is one of the models embraced here.”

An example of this would be the team’s approach to obesity, which is a major risk factor in heart disease. Whereas weight loss is an area that may have previously been handled at a primary-care level, cardiology takes an active and innovative role at Rochester Regional Health.

The team at RRH uses injections of glucagon-like peptide-1 receptor agonists, also known as GLP-1 receptor agonists, to help some patients with weight