Shaping the Future of EP Through Advanced Signal Processing and Analysis:

Interview with Andrea Natale, MD and Matthew Dare, CEPS

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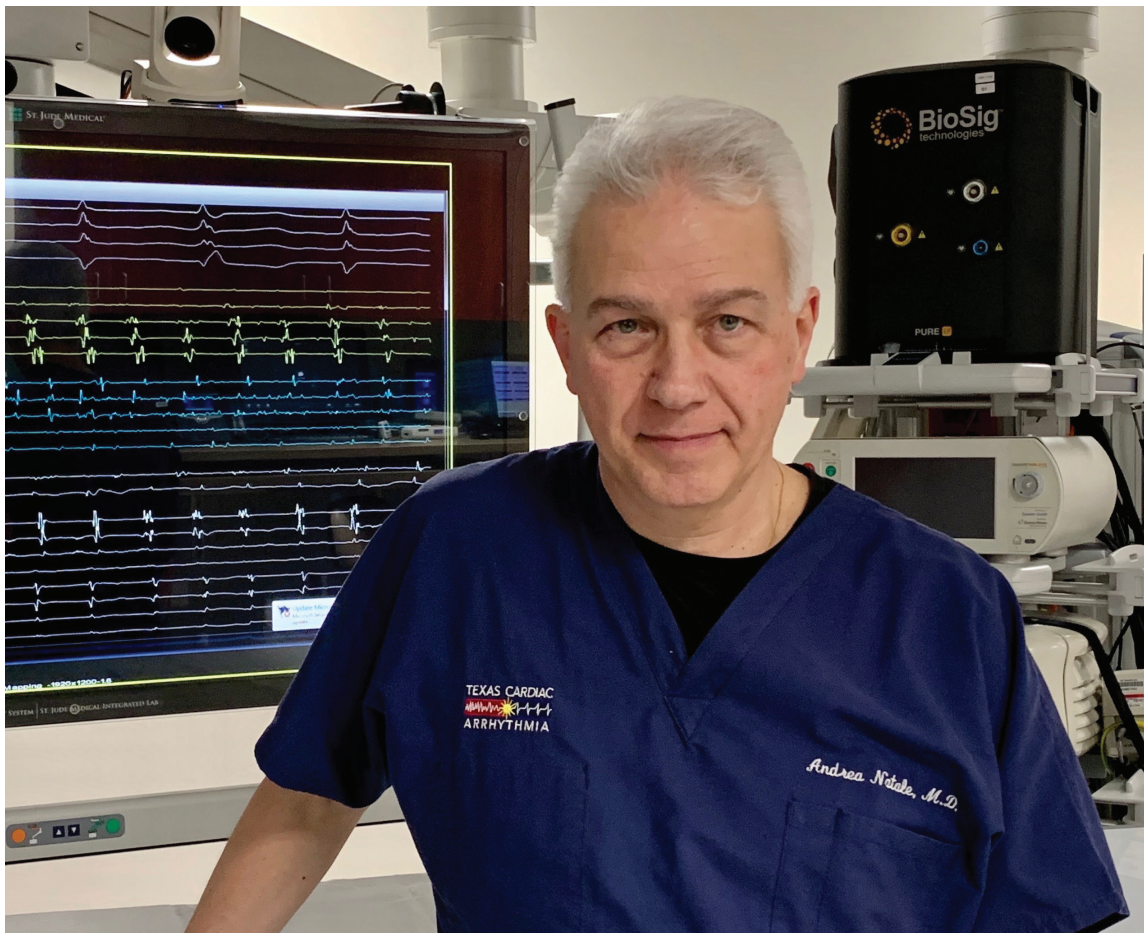

Figure 1. Andrea Natale, MD in the EP lab.

The field of electrophysiology (EP) has drastically evolved over the last 20 years with major advances in mapping technologies and imaging modalities. As this field grows and we continue to strive for better understanding and treatment of complex cardiac arrhythmias, it is important to stay focused on the foundational principles of this entire specialty: the interpretation of intracardiac electrograms. Recent developments in the area of signal processing and analysis (SPA) are driving improvements in the quality of intracardiac electrograms to help us better understand electrical tissue properties and precise activation patterns. Advancements in SPA coupled with modern mapping and imaging technologies could help improve the current diagnosis and treatment of complex arrhythmia patients.

The interviews with Andrea Natale, MD and Matthew Dare, CEPS (Research and Technology Coordinator) are designed to explore the current shortcomings in signal processing, and describe their early experience with the PURE EP™ System (BioSig Technologies, Inc.) at St. David's Medical Center in Austin, Texas.

Figure 2. Matthew Dare in the control room.

Q&A with Andrea Natale, MD

In your experience, what are the biggest shortcomings with current signal acquisition technologies?

What I've observed in recent years is a primary focus on the advancements of mapping capabilities. This was a critical phase of innovation in the field of electrophysiology. I believe the biggest shortcoming at this stage, though, is the inability to see detailed and complete intracardiac signals. Indeed, existing technologies use classic hardware design to amplify and filter intracardiac signals. A successful solution may lead to a clearer understanding of the mechanisms related to complex cardiac arrhythmias. There is also a growing need to expand current technology in signal acquisition and processing to include data-enabled algorithms and analysis.

Our physician team recently began using the PURE EP™ System, a novel signal processing system developed by BioSig Technologies, Inc. This technology relies on a totally different hardware design, allowing the user to see intracardiac signals across a broader range of cardiac frequencies without significant signal attenuation. This is especially important for visualizing complex, low voltage, and fractionated electrograms.

Additionally, current technologies struggle with environmental noise from all the other equipment in the EP lab. The PURE EP™ System has a low-noise design, which can be very useful in those labs not equipped with their own power station, as we have at St. David's Medical Center.

What is the clinical value of seeing intracardiac signals across a broader range of frequencies, and why is it important?

Complex arrhythmias such as atrial fibrillation (AF), ischemic ventricular tachycardia (VT), and PVCs are associated with composite arrhythmogenic substrate that can further be compounded by the presence of scarred cardiac tissue. Those intracardiac signals can be highly fractionated and difficult to detect and analyze. Fractionated signals are defined as being of higher frequency and of extremely low voltage in some cases. These are

the types of signals that I am actively looking for to guide ablation treatment.

In our experience, the PURE EP™ System allows for linear acquisition of multifactorial electrograms coupled with a wide dynamic range. This provides accurate and proportional visualization of signals, regardless of their respective amplitude and frequency.

A useful example of these characteristics is seen during pace mapping when we are looking for the site of earliest activation. Oftentimes, the signal is impossible to see because of system saturation. The PURE EP™ System offers an amplitude window of 500 mVpp, which prevents saturation as well as provides a quicker recovery to baseline and fuller visualization of all the signals.

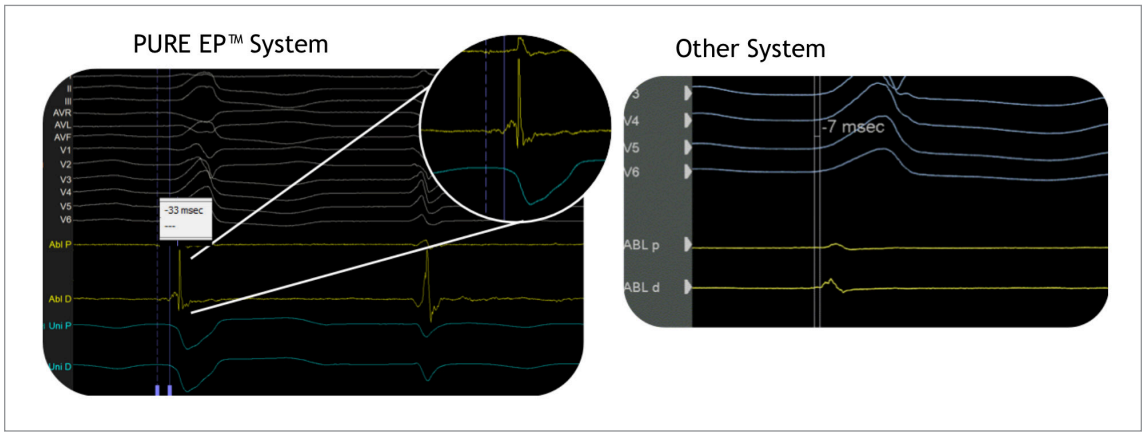

Figure 3. **Example of PVC procedure, comparing signals at a critical location.**

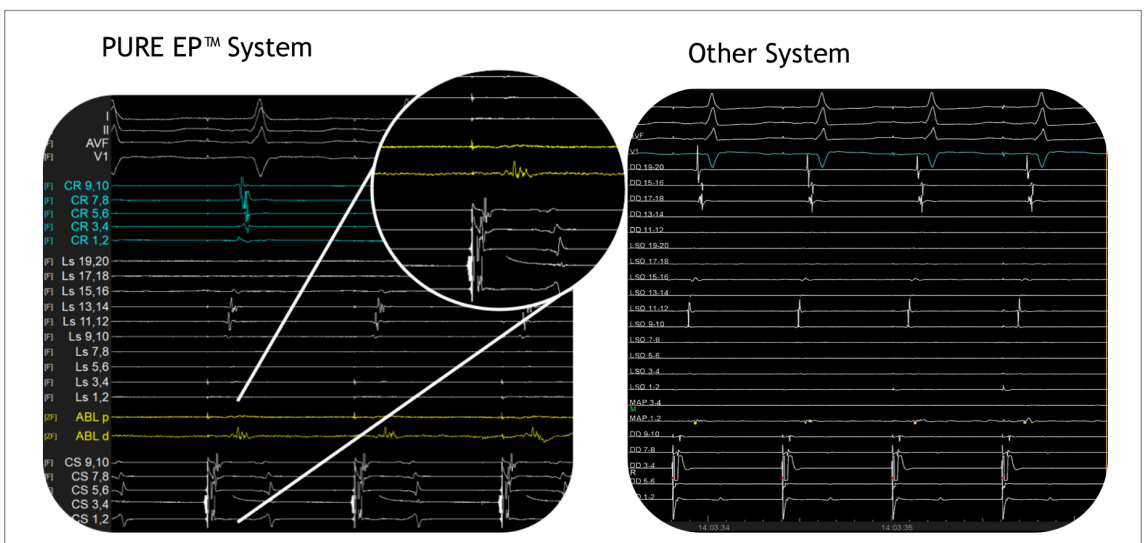

Figure 4. **AF with pacing on CS 3,4 with a clear visualization of signals post pacing without system saturation.**

You and your team were the first users of the PURE EP™ System. Can you tell us about the ongoing PURE EP™ clinical trial and your main observations?

The PURE EP™ study is designed to help us evaluate the signal quality and measure clinical impact of the PURE EP™ signals. We have enrolled more than 50 patients to date, and have already had a blinded panel of EP independent reviewers assess a set of the signal samples. I would say we are definitely seeing more signals of interest on the PURE EP™ system. It does appear to do a better job of seeing the smaller signals regardless of the catheter that is being used.

Can you guide us through a few signal examples and their clinical relevance?

The first example (Figure 3) shows a PVC procedure, comparing signals at a critical location. The PURE EP™ System shows an early activation with a timing of 33 ms. It is interesting to observe the local depolarization actually preceded by a far field signal component as shown on the PURE EP™ System.

This is a very good example of the additional signal information we are seeing on the PURE EP™ System, which may lead to a clearer understanding of the mechanisms related to complex cardiac arrhythmias.

The second example (Figure 4) shows atrial fibrillation with pacing on CS 3,4 with a clear visualization of signals post pacing without system saturation. It is also interesting to observe the fractionated potentials on the distal ablation electrode, which measures an amplitude of ~0.2 mV peak to peak.

How do you think signal processing and analysis technologies could influence procedures in the future?

We are still early in our evaluation, but I would say any significant improvement in signal acquisition and processing that allows EPs to see more intracardiac signals of interest can potentially help us be more efficient and effective in our treatment. We are exploring and discovering the clinical value of seeing detailed and complete intracardiac signals in our clinical practice as well as through the clinical trial work that is being conducted. As I said at the beginning, there is no doubt in my mind that data processing is going to play a major role in the understanding and treatment of complex cardiac arrhythmias. The quality of the signals is of utmost importance in this case, as advanced signal processing softwares depend on the quality and the completeness of the data that is being utilized.

Q&A with Matthew Dare, CEPS

Tell us about the EP program at St. David's Medical Center/Texas Cardiac Arrhythmia Institute.

I've been with St. David's Medical Center/Texas Cardiac Arrhythmia Institute for 13 years. When I started back in 2007, we had only a single dedicated EP lab. We opened our second EP lab a few months after that. In 2008, we partnered with Dr. Natale and the Texas Cardiac Arrhythmia group to create TCAI at St. David's Medical Center. After that, we began investing pretty heavily in upgrading our facilities, and within about a year and a half, we grew from two dedicated EP labs to four. In that time, we went from doing a couple hundred complex arrhythmia ablations a year to just over 2000 (primarily AF and VT ablations).

In 2014, we started planning for a new dedicated EP pavilion, which would involve adding floors for an EP space as part of a vertical expansion of our existing hospital space. The new center opened in August 2019. In this new space, we have six dedicated EP labs. All labs are hybrid capable, but we do have one designated extraction/complex procedure lab for procedures such as major lead extractions or convergent ablations. In addition to the dedicated EP procedural space, we built 12 prep bays, an outpatient unit, and an eight-bay dedicated EP PACU as part of the expansion.

What are the common technical challenges seen within the EP lab environment?

One of the big things we looked at when we were designing the overall labs was how to deal with environmental and electrical noise. Both within our lab and in other labs we've worked with at other hospitals, we've run into issues with environmental noise from large equipment, cabling runs, etc. Since we were building this new center from scratch, we were able to control what was above, below, and next to the labs, so there are no sources of high-voltage electrical noise or significant environmental EMI anywhere near any one of these labs. We spent a significant amount of time and money on the electrical work, including doing a completely independent grounding system for each lab separate from the rest of the hospital, as well

continued on page 24

Signal Processing & Analysis

continued from page 23

as a centralized EPS and power conditioning system to manage some of the issues we've had in the past with electrical power coming into the lab. When you have voltage fluctuations, it can cause electrical noise or potentially damage sensitive electrical equipment.

Can you share your experience on how the PURE EP™ System interfaces with existing lab equipment?

We did the first cases with the PURE EP™ System in February 2019. It's a separate system from all of our existing equipment, so you need a video connection to your display system and electrical connection to the catheters. We initially had the individual jumper on the electrodes to our 3D mapping systems, our EP recording system, and the PURE EP™ System. While that's still the case, the original cases last February were with the first-generation unit versus the current one we're using now, so we've been able to streamline that connectivity using bundled connections. We've come up with better ways to connect the catheters and worked with the folks at BioSig Technologies to streamline the whole process. On the catheter connection side, we've developed a nice workflow and have dedicated connectivity for our recording system and 3D mapping systems. Early on, we provided BioSig with some feedback. They just deployed an updated software version based on our recommendations, so I am really excited about that.

Based on your experience managing multiple labs in parallel in one of the busiest EP centers in the nation, what are the key elements of a successful new technology introduction?

I think it goes back to the original lab design — you want to make sure when you design the lab that you build it with maximum flexibility in the future both from a video connection and room standpoint, including where to place your booms, conduits to run cable, etc. Those kinds of things are really key in integrating any new technologies. EP is such a fast-growing field with a lot of new exciting technologies always rolling out, that you want to make sure that you plan for this when you build your lab, and that starts with the actual lab design.

The next consideration is workflow planning. You want to make sure that everybody involved understands the workflow and has gone through the workflow before you actually install the equipment. Therefore, you know where the equipment is going to go, and how it's going to hook up to other systems.

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Figure 5. Matthew Dare, CEPS in the EPS/Power conditioning room.

Figure 6. TCAI team.