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Exec Chat: Abbott Bets On Modular And Leadless Devices To Be The Future Of Cardiac Rhythm Management

by Reed Miller

Medtech Insight interviewed Leonard Ganz, a veteran cardiac electrophysiologist who recently joined Abbott's cardiac rhythm management business as its divisional vice president of medical affairs and chief medical officer.

The cardiac rhythm management technology industry is shifting from implantable devices with difficult-to-explant transvenous leads to leadless devices integrated into modular systems.

Abbott is competing with *Medtronic* and *Boston Scientific* to lead this change. The US Food and Drug Administration recently approved Abbott's Aveir VR single-chamber leadless pacemaker based on the results of *LEADLESS II* trial. (Also see "*Minute Insight: Abbott's Aveir VR To Take On Medtronic's Micra In US Leadless Pacemaker Market*" - Medtech Insight, 4 Apr, 2022.)

Aveir VR is indicated for significant bradycardia, chronic atrial fibrillation, and severe physical disability. It is the only leadless pacemaker designed that can be retrieved if the patient ever needs a different device, according to Abbott.

Medtech Insight talked to Leonard Ganz, an experienced cardiac electrophysiologist who recently joined Abbott's cardiac rhythm management business as its divisional vice president of medical affairs and chief medical officer.

Q ***Medtech Insight:*** **You're fairly new to this role at Abbott. Can you talk a bit about your background and how you came to Abbott?**

A Leonard Ganz: I've been at Abbott since early March and, prior to that, I was a practicing cardiac electrophysiologist in the Pittsburgh area for a number of years, working in both academic and private hospital settings. I've done a fair amount with the Heart Rhythm Society as the chair of the Education Committee and on the Board of Trustees, and also with industry medical advisory boards, but this is the first time I've worked full-time in the industry and not practiced cardiac electrophysiology.

DR. LEONARD GANZ, DIVISIONAL VICE-PRESIDENT OF MEDICAL AFFAIRS AND CHIEF MEDICAL OFFICER FOR ABBOTT'S CARDIAC RHYTHM MANAGEMENT BUSINESS *Source: Abbott*

My new role as Divisional Vice President of Medical Affairs and Chief Medical Officer has been a very exciting transition for me. It's an exciting time in [cardiac rhythm management (CRM)], and an exciting time for Abbott.

Shortly after I began here, we got the approval for Aveir VR single-chamber leadless pacemaker.

We received FDA approval in early April, but the majority of patients who are candidates for pacemakers are Medicare patients. So, they were not candidates for the Aveir VR until recently when CMS approved the *Aveir VR coverage-with-evidence development post-approval study*.

We had a number of patients with commercial insurance who were implanted with the device between April and now, but the younger population is not the majority of pacemaker patients and, like I said, this is relatively narrow slice of the overall pacemaker population. So that CMS decision will bring this to a lot more patients.

> And we've got *the dual-chamber leadless pacing trial ongoing*, which has been very exciting. So, all in all, it's been busy, but a great transition for me.

"If we can develop technologies to provide the same benefits without leads, then we really obviate the potential for these long-term complications, lead malfunction, lead failure, and then chronic infections in patients with leads and help patients live healthier lives." – Leonard Ganz

Q **As a clinician, why do you think it is so important to have these leadless options for CRM patients?**

A Ganz: The standard types of pacemakers that we've had for close to 60 years now and the implantable defibrillators, which we've had for several decades, work really well. Those devices have been shown to help make people live longer and improve their quality of life in many different settings.

Our patients are living longer and longer and we're putting devices in younger and younger patients. So, when you're thinking about the need for a functional device in someone over decades, the question is how do we do it better?

We developed technologies to extract chronic leads and put new ones in. But over time, the idea emerged that maybe we can do it without leads.

The technologies within leadless single-chamber pacemakers can provide similar benefits in terms of improving and prolonging lifespan, but without the downsides that leads bring. And the potential downsides with leads are not just the fact, that over the long-term, they may be less reliable than other parts of the system. There are several long-term complications that develop in patients that can be very serious that relate to leads.

For example, if a patient develops a bacteremia and infection in the bloodstream from some other source – pneumonia, cellulitis, or some other type of infection – chronic lead systems can become infected.

And it's virtually impossible to clear a chronic infection once it involves leads. And what we typically need to do in those situations is extract the leads. And this can be very difficult if leads have been in for many years because the body forms scar tissue around them, and that that lead extraction procedure poses risks to patients.

So, if we can develop technologies to provide the same benefits without leads, then we really obviate the potential for these long-term complications, lead malfunction, lead failure, and then chronic infections in patients with leads and help patients live healthier lives.

Q **What technological innovation or innovations has made it possible to develop these leadless systems now whereas it was not possible 15 or 20 years ago? Or was it just the growing awareness of the potential complications with leads that spurred the development of these technologies?**

A Ganz: There's been increasing awareness, over the last 20 years that it would be great to do this without leads. The initial technologies to try to do leadless pacing were developed over the last 10 or 15 years.

The technologies that allowed this to be possible include the miniaturization of circuitry and batteries, because obviously, you're going from a pectoral device with substantial size and volume to a much tinier device that sits within the heart. To be able to have a battery in those, in a device that would provide substantial longevity, was really a technological feat.

One of the things we're especially proud of with the Aveir single-chamber leadless

pacemaker is the battery longevity. It's substantial and it far exceeds other commercially available leadless pacemaker products. It will provide a device that in many patients will last 10 years based on [International Organization for Standardization (ISO)] standard settings.

Q **In the past, there was some discussion within the field of trying to find ways to wirelessly recharge these devices. Is that still a consideration?**

A Ganz: There were thoughts fairly early in the development of pacing systems about a rechargeable battery, but that approach was abandoned early on because of the concern that a patient might not be compliant with their therapy.

Rechargeable batteries are used in other implantable electronic devices that are not necessarily life-prolonging or necessary moment-to-moment – some chronic systems for pain control, for example, can be rechargeable, and even some cardiac devices, but not ones that are required moment-to-moment to be always powered up.

"Over the last 10 years, the electrophysiology community has moved to this philosophy that you should be thinking about retrieval when you're putting in a device in and implanting it in a way so that it'll be easily retrieved or more easily retrieved in the future." – Leonard Ganz

Q **Can you talk more about the dual-chamber pacemaker evaluated in the *Aveir DR i2i Study*?**

A Ganz: "i2i" stands for "implant to implant," because in order to make dual chamber technology work, the devices have to communicate with each other, back and forth, bi-directionally for every heartbeat.

Our scientists and engineers had to develop an entirely new communication system for these devices, so that's what the idea is.

And that clinical trial was started in February of 2022 and it is ongoing globally. We're very excited about it. Hopefully we'll be able to share more with you about it in the not-too-distant future.

Q **Do you expect leadless devices to eventually take over most or all of the cardiac rhythm management device space or will there always be a substantial number of patients who need a system with a transvenous lead?**

A Ganz: It's a good question. There is a large army of patients out there who have existing leaded system, whether we're talking about pacemakers, ICDs, or cardiac resynchronization therapy (CRT) systems and the majority of those patients are doing well. Those patients will continue to require traditional pacemaker, ICD or CRT equipment for generator changes and their needs won't go away.

Additional areas for investigation include nonvascular ICD systems that would also have a pacing capacity – whether it's for slow heart rhythms or for antitachycardia pacing – to terminate ventricular arrhythmias, and also systems that could do more physiologic pacing leadlessly.

There's a growing movement over the last couple of years for 'conducting-system pacing.' That tries to engage the specialized conducting system in the heart to create a more physiologic contraction of the heart. We've done this for many years with CRT, but a conducting system pacing tries to do this by pacing deep within the right ventricle's ventricular septum.

There are ongoing trials, looking at that longitudinally in terms of patient outcomes, both for patients who would, at this point, be considered candidates for CRT, as well

as patients who are candidates for other types of pacemakers.

Right now, we accomplish CRT with a lead in the in the right ventricle (RV), and a lead in the coronary sinus branch that will pace the left ventricle and there may be an atrial lead. Conducting system pacing has the potential for doing it with one ventricular lead deep the ventricular septum. You might also need an atrial lead depending on the circumstances, but one lead deep in the septum might take the place of both the RV and the coronary sinus branch lead.

Clinical data would have to validate that conducting system pacing is either equivalent to or superior to traditional CRT. The step beyond that would be trying to develop a way to do that leadlessly.

And people are very enthusiastic about where conducting system pacing may go. And another very exciting possibility would be if there were a way to marry leadless pacing with conducting system pacing. But that's a real technological challenge and is even a bit further in the future.

Q **Other companies like Medtronic and Boston Scientific are also developing leadless CRM technology, so how would you differentiate what Abbott is doing in this field?**

A Ganz: The way we've developed Aveir VR sets us up for some of the more 'forward' questions you're asking.

There are several important features that distinguish Aveir VR from the other leadless pacing product on the market. The first is our fixation mechanism. We have a helix on the end of the device, and the device is actively fixed into the target tissue, which is a different fixation mechanism than the competitor.

One advantage to this fixation mechanism is that we can test the spot before we

fixate. We can get a sense for whether the site that we're in is going to be a good site for pacing before we fixate the device. And we call that mapping.

And, as a result, in our *LEADLESS II clinical trial*, the vast majority of implants did not require repositioning of the device once it was fixed because we can do that mapping.

Another advantage of Aveir VR is that it is designed to be explanted when the battery runs down, so we've developed a retrieval catheter. So, the device is fixated by turning the device through the delivery catheter clockwise, and it's explanted with the retrieval catheter by turning the device counterclockwise. We have an extensive experience with retrieving devices.

The battery can last for many years, but rather than just abandon it and try to find another spot in the heart for a second device, investigators and implanters will be able to retrieve the one that's in there and put in a new one.

Over the last 10 years, the electrophysiology community has moved to this philosophy that you should be thinking about retrieval when you're putting in a device in and implanting it in a way so that it'll be easily retrieved or more easily retrieved in the future.

Another aspect is the Aveir VR device electronics are designed to be enabled by future software, upon regulatory approval, to support dual chamber pacing in the future. As mentioned previously, dual chamber pacing is currently in clinical trial and limited to investigational use only.

I've gone to a number of our Aveir VR physician training programs and talked with physicians, most of whom are quite familiar with the existing products on the market and are learning about our product.

The thing they seem to be most enthusiastic about with Aveir VR are the chronic retrievability and the potential for future updates.

"Now that we have a retrievable device, it will open up even single-chamber leadless pacing to younger patients to be considered for it where they might not have been previously." – Leonard Ganz

Q **Is there anything else you'd like to mention about Abbott's investment in this technology?**

A Ganz: The specific advantages of the Aveir VR single-chamber leadless pacemaker may make leadless pacing available to more patients than previously considered.

For example, a younger patient who might be a good candidate for a single-chamber leadless pacemaker might not have gotten one because the physician thought 'What am I going to do? Keep putting new devices in every time the battery runs out?'

There's only so much room – or as some of our physicians like to say, real estate – in the right ventricle.

Now that we have a retrievable device, it will open up even single-chamber leadless pacing to younger patients to be considered for it where they might not have been previously.

The advantages of the Aveir VR may expand the single-chamber and leadless pacemaker market some, even on its own.