

AHA's National Cardiac Implantable Electronic Device (CIED) Infection Initiative Podcast Series

Episode 1—Treating Pacemakers and Other Implantable Devices Infection: A shared decision between patients and healthcare professionals

00:00-00:52

Intro: This podcast is part of the AHA's National Cardiac Implantable Electronic Device Infection Initiative. The goal of this initiative is to address the gaps in awareness, detection, and appropriate treatment of pacemakers and other implantable device infections. For the latest information about upcoming events and other resources on this topic, please visit: heart.org/treat2beatciedinfection.

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00:53-01:43

Liz Olson: Welcome everyone to this episode of “Treating Pacemakers and Other Implantable Device Infections: A shared decision between patients and healthcare professionals.” The use of pacemakers and cardiac implantable electronic devices or CIEDs is becoming more and more common. While these devices extend and improve people’s lives with minimal problems in most cases, for patients who experience infections related to their devices, gaps and delays in guideline-recommended care can lead to preventable illness, disability and death. Data has shown that these kinds of gaps and delays in guideline-recommended care are all too common. Improved awareness and timely diagnosis are essential to help save lives. Today we welcome two speakers Dr. Miguel Leal and Ms. Trudie Lobban to have a conversation on how the treatment path is a shared decision between patients and health care teams.

01:44-02:14

Liz Olson: Before we begin our discussion today, I’ll introduce our speakers. Dr. Miquel Leal is an associate professor in electrophysiology at Emory Health Care. His passion for medical education and mentorship lead him to serve as program director of both the Cardiovascular Disease Fellowship Program and the Clinical Cardiac Electrophysiology fellowship program from 2016 until 2021. He’s contributed as co-author of several clinical practice guidelines issued by the American Heart Association, the American College of Cardiology and the Heart Rhythm Society.

02:15-02:43

Liz Olson: We’re also pleased to welcome Ms. Trudie Lobban, the founder of the Arrhythmia Alliance, the AF Association and STARS. All international nonprofit organizations providing information, support, education and awareness on all arrhythmia, syncope, and atrial fibrillation. Trudie sits on a number of medical boards, research committees and steering groups. In addition to being council member of committees and advisory boards, she is also an author and co-author of numerous medical papers relating to cardiac arrhythmias and AF.

02:44-02:48

Liz Olson: Dr. Leal, Trudie, welcome today. Excited to have our conversation.

02:49-03:14

Dr. Leal: Well, thank you Liz. It is a pleasure and a privilege to be part of this very important conversation. And I'm very happy to be here sharing this time and this space with you, and with Trudie, who I had the opportunity to meet approximately a year ago when the American Heart Association was officially launching its very important initiative towards increasing awareness and creating mechanisms to effectively prevent infections associated with cardiac implantable electronic devices.

03:15-04:00

Trudie Lobban: Thank you, also. Miguel, it's good to see and hear you once more. It's been too long. It's so important that we raise greater awareness of the symptoms and the signs of potential device infection and the action to take. We need to get this message out, not just to health care professionals, but to people living with implantable devices. So, although it's rare, I think you know it's part of what everybody needs to know as their ongoing treatment—to ensure they are receiving optimum treatment. Because we know these devices are lifesaving in many instances. But we need to make sure there's no underlying infection, and if there is, the action is taken as quickly as possible. So, we welcome this podcast. Thank you.

04:01-04:10

Liz Olson: Excited to have the conversation today. Dr. Leal, I will start with you. Can you walk us through the journey of a patient with an infected pacemaker from the health care provider perspective?

04:11-05:06

Dr. Leal: Certainly, Liz. And it's a great way to start our dialogue here today. As we know, devices such as pacemakers and defibrillators have been responsible for tremendous improvements in the health care of millions of people since their original inception. Pacemakers have been around for seven decades or so, and defibrillators have been around for at least three, if not four decades, depending on how you count it. And you can imagine that as any medical procedure, there is a statistical chance, no matter how low and infrequent, that some of those implants will complicate. And one of the most feared complications that can arise from a device implant is a device-associated infection, which can manifest itself in many different ways. It could be a quite obvious surgical site infection. If the suture line never closes well, or if the place where the device is implanted—the site of the implant—looks swollen or red or painful or tender to the patient.

05:07-05:35

Dr. Leal: So these are things that will call the patient's attention that something is wrong. That the healing process is not going the way it should. The way it was announced to the patient that it should. There are also other subtle forms of disease. For instance, there are more indolent forms of infection that may manifest themselves with systemic symptoms. Patients will feel nothing more than just, maybe, perhaps a fever, or some chills, or some lethargy, some apathy, lack of energy, lack of stamina.

05:36-06:59

Dr. Leal: And that's why sometimes these infections can be obvious, but often they are not. They can be subtle. And the problem with the subtlety of the presentation is that it can lead to a very, very delayed act of seeking formal medical attention. From an additional perspective with this, it is certainly a very disheartening experience to the patient because when you think about it, there is a lot that is invested in a decision to sign up for a pacemaker implant or a defibrillator implant. The patient and the family will do a lot of reading, will discuss with their medical provider, or the clinician in charge of their care, all the pros and cons. So, there is this expectation the procedure will

go well, and that that device will help the patient from that point forward. So, any setback, especially a relevant setback, such as infectious complication, can also cause a significant psychological impact on the patient as I'm sure we're going to hear from Trudie because this is another part of the care of these patients that cannot be underestimated. So it's a very different presentation in terms of how the patient will show up to the clinician's office. It could be with an obvious surgical site infection that may happen a week or two or three after the implant. Or it could be after the patient has been around many different specialists: internal medicine, family medicine, infectious disease specialists and other colleagues trying to find out what exactly is the problem. What's making the patient feel unwell?

07:00-07:06

Liz Olson: Trudie, from the patient's perspective, what does that journey look like for them to deal with an infected pacemaker?

07:07-07:51

Trudie Lobban: So for the patient, obviously they've been feeling unwell. They've had symptoms. Hence why they've had to go and eventually have a device implanted, or it may have been as an emergency they have the device implanted. And so, it's a huge sigh of relief that they've received the treatment, and they can be restored back to a healthy, active person—no longer a patient. However, what we must not forget to inform them is the risk of an infection. Now, all too often this is conveyed to the patient at time of implant, and they may be given antibiotics at discharge. But what about months, or even years later?

07:52-08:57

Trudie Lobban: When if all goes well, you almost forget that you've got a device other than perhaps an annual checkup. You know, the whole purpose of having this this device is to restore the patient back to a person. So, I think there needs to be gentle reminders of the signs and symptoms, and also that an infection can occur because of something else in the body, and the infection traveling to the device. So for the patient, the journey, they're often totally unaware. They may have had an infection in their foot. They wouldn't even associate that with their heart or a device that may have been implanted five-, six-, seven-, eight-years ago, and yet they could be having a fever feeling unwell, etc. There isn't always a soreness around the device. So there may not be anything at the site of the wound. And remember, these devices are so small now, the implant. These scars heal incredibly. You know the great thing that patients almost forget that they have them implanted, and that's what we want. We want to restore normal life.

08:58-09:30

Trudie Lobban: But I do think we need to make sure that patients are aware. So, on their journey for the rest of their life with this device, in most cases. Yes, it is a life saving device, but to be aware. So that if they have a temperature, an infection, whatever, when they see whether it's their primary care physician, the foot doctor, you know, whatever doctor they may be seeing or not, they should mention that they have a device. Just in case there's any infection.

09:31-10:33

Trudie Lobban: We need greater awareness with the clinicians, not just the heart doctors, electrophysiologists, the heart rhythm specialists, are only too aware of device infections. But maybe in general cardiology, or maybe at the podiatrist or any other department will not necessarily be aware. So it's a much, much wider readmit, just like we need to make sure the patient, the caregivers, the loved one, the families are all aware that not just in the few weeks after

implant, but months or years later, there is still, albeit a very low risk, there is a risk of an infection, and to take prompt action. And to draw this to the attention of the team of doctors or nurses you might be seeing at that time who may not have any training in cardiology. So it almost becomes part of responsibility of the patient, unfortunately, to draw attention to their device. And has the infection spread? Is it affecting my device?

10:34-10:42

Liz Olson: Dr. Leal, this is a complicated situation, as Trudie's outlined for us, and as you've outlined for us. So how can you create a shared space for patients and providers?

10:43-11:15

Dr. Leal: So Liz, thanks for bringing this topic up. I think one of the best developments that has taken place in the relationship between a physician, a clinician in general and a patient, in today's day and age is the concept of shared decision-making. For too many years we had paternalistic practices by which a physician would dictate what he or she thought was the best course of care for a patient, and the patient was expected to simply accept it. And here the risks and benefits and essentially play along with what he or she was provided as the best available data.

11:16-12:23

Dr. Leal: Fortunately, that has evolved significantly. We live in an era of information, an era where patients and families can obtain different sources for knowledge, for information, and I think shared decision-making is all about a truly informed decision about the plan of care and the course of care that a patient should go through. So bringing it into this era of internal devices, bringing it into the spectrum we're discussing here today. From the very beginning, when the decision is made to have a pacemaker or defibrillator implanted in a patient, it is ideal that this conversation took place with a very thorough discussion of the short- and long-term consequences of having and not having the device implanted. So the patients and families, with whatever time they have allowed—sometimes the decisions have to be made a little more quickly, other times that is the opportunity to sit on them for a few days until a final decision can be made—patients and families can truly participate and advocate for their own values and wishes and desires. When it comes to how aggressive or conservative their care will be.

12:24-13:13

Dr. Leal: So if an infectious process takes place, which as Trudie correctly alluded to, this is something that we all do not like to see. This is something that is one of the worst possible outcomes because after the implant of a device, you expect that device to serve you well for the entire battery longevity of that device. Be it eight-years, 10-years, 14-years or so. So infectious process happens to interrupt that sequence. It puts a significant curve ball in the narrative. And it's important that patients and physicians, and when I say physicians, I refer to any healthcare professional caring for that patient. So that includes nurses, nurse practitioners, physician assistants, which are every part of the medical ecosystem that we live in. It is important that that conversation is very clear and transparent about the risks and benefits of the different approaches involved.

13:14-14:12

Dr. Leal: But many times, it is important to advocate for aggressive intervention to remove the device. And when I say the device, it's not just the pulse generator, the so-called battery packet so to speak, but the entire system, including the implanted wires, or cables or leads. Because the device infections they tend to perpetuate themselves. They may respond to a course or two of antibiotics. They may have the patient feeling a little bit better for a few weeks, but when they come back, they

tend to come back worse, because now they have a more systemic approach. It can affect other organs, such as the liver and the brain, the kidneys, the gut, the lungs and many other areas of the body that were not necessarily affected when the infection was first discovered. So these conversations have to be very explicit and very clear. There is enough information. There are enough data published in today's medical literature. So these pieces of information, which are very precious to this discussion, have to be laid out in front of the patient and their families.

14:13-14:41

Dr. Leal: So, when difficult decisions have to be made, such as for instance, proceeding with the extraction of a system that may have been implanted 10-, 15-, 20-years ago, which is not necessarily a decision without risks themselves. But when those decisions need to be made, it is important that everybody is on board. And to approach this narrative, this dialogue, with a shared-discussion approach, with a shared decision-making approach is certainly in everybody's best interests, especially the patients.

14:42-17:23

Trudie Lobban: So shared decision, fantastic! We absolutely endorse it and welcome it. Unfortunately, though, for some health professionals, this is a check box exercise. Did you have a shared decision discussion with your patient? Oh, yeah, I told them they needed a pacemaker. I told them they needed this drug or whatever. So, we need better education and understanding for the patient and the health care professional, and to be able to sit down and discuss. However, time is so short these days. And the number of patients and the time spent with their physician, their nurse, and I agree with Miguel that it needs to be whatever touch point you have throughout your journey with healthcare professionals, every one of them should be having discussions with you. So one of the things we've done at Arrhythmia Alliance in partnership with Mended Hearts was to develop a discussion guide, and that's available to download from our website. And it is for patients to prepare, to educate, to empower them, to have the confidence to sit down and discuss and make an informed shared decision. Because it's very difficult for a physician to go right back to the beginning, explaining everything, when there's another 10 patients waiting to come in outside. But equally, it's very difficult for the patient who maybe has never ever heard...most have heard of a pacemaker. Most have not heard of an implantable cardiac defibrillator, or a CRT device, or whatever. So we need to be giving them this information. And I think it's important for doctors' offices to have the information from organizations such as ourselves. They can go out in the first letter to the patient, or when they first come in, so that they can read. Because you know, studies have also shown you're very emotional. You're very anxious. You're unwell. You sit down with this person you've never ever met before, and they start telling you need an operation. You need a life saving device. You're frightened. You don't hear all that's being said. Suddenly, words are being used you may never have come across in your vocabulary before. One of the things we always recommend is that patients take a friend, a relative, a colleague, whatever with them. Take a notepad because saying they made a joint decision isn't accurate if they haven't understood. So it's equipping patients and caregivers with that information for them to go away and to be able to read and digest after the appointment, and also to be able to come back and ask more questions.

17:24-18:17

Trudie Lobban: I always say there's three pieces of a jigsaw for the patient pathway. First and foremost, there's the patient, but they're not a patient until they get a diagnosis. There's the healthcare system. Without our doctors, they wouldn't be patients, and they wouldn't be able to receive treatment, restoring them back to a person. There's also the organizations such as ours. We're here to offer the education, the information, and the support and the time. We can't give the

medical information, but we can give the general education. So, we need to work as one, collaboratively to make sure that the person entering into the system, goes through it understanding what is required, the consequences, and they are able to make those informed, shared decisions. Obviously with guidance and recommendations by their physician, but fully understanding the consequences.

18:18-19:00

Trudie Lobban: We need to be educating our doctors how to speak with our patients in language that they understand, and for patients not to be scared or anxious to say, "Excuse me, doctor. I don't understand what you just said. I've not heard that word before." And also, to know where they can go away, or they can call us and ask questions that they either ran out of time or didn't like to ask. Even though we always say, you know, "Ask your doctor, ask your nurse anything. They're there for you." But we need that joined-up approach and shared decision-making is vitally important, but it does need to be shared, fully understood by both parties.

19:01-19:21

Liz Olson: I can imagine what a frightening experience this can be for patients and their families. Dr. Leal, when you are working with these patients, what can you do to manage some of the fears about what they're going through, and also some of the misconceptions about the risk?

19:22-19:50

Dr. Leal: Thank you, Liz. Lead extractions and procedures that involve extracting implanted, endovascular devices have always received a healthy degree of respect in the medical field because when these procedures began to be performed back in the seventies and eighties, the technology available to perform them correctly was not what we have today. And consequential to that, the morbidity and even mortality of these procedures was not small.

19:51-21:46

Dr. Leal: If you look through the medical literature looking at how does treating these patients with the most aggressive course of care, which is also the most likely course of care to result in a good clinical outcome. If you look at how lead extractors have evolved over the last two, three decades. We have fortunately made tremendous strides in progress, which allows us to open this conversation with our patients today in a much less somber tone than say, if this conversation was had, or was held in the early nineties or even early 2000s. There are now, in most electrophysiology fellowship programs, opportunities to either be exposed to or to truly perform lead extraction procedures in the right setting with cardiovascular surgery back up with all the procedural preparedness that these types of operations require and should involve. The consequences we are having now...a larger number of professionals that are apt to successfully and safely perform lead extractions, and I keep referring to this lead extraction terminology, because as I mentioned before and Trudie also alluded to, sometimes it's really hard to tackle this problem halfway through by proposing conservative measures, such as again suppressive antibiotic therapy sometimes for weeks or months, or sometimes lifelong. In order to provide a patient with the best opportunity for a cure for a truly effective treatment many, many, many times, and this number can be reflected well greater than 90% of the situations, a full system extraction is required. This is not something that I am saying here out of my own personal experience, but something that has been reported in many, many clinical studies, and also summarized in clinical practice guidelines by the professional societies that we work with.

21:47-22:26

Dr. Leal: So, because the procedure which still deserves a significant degree of respect and reverence as any invasive procedure should. But because this procedure has improved its safety outcomes, and also its performance, its efficiency altogether. It is reassuring to patients, to some degree, to understand that they are signing up for a procedure that has a mortality rate of well less than 1%. It has a risk of major complications that is not significantly different than other procedures that patients routinely sign up for, such as receiving a coronary stent or undergoing the ablation of another type of cardiac arrhythmia.

22:27-23:46

Dr. Leal: These procedures, still as I said, and I emphasize, should be undertaken with caution, with care. Ideally, in high volume centers by very experienced operators with a significant amount of backup, which also includes cardiothoracic surgical backup. In most, if not all instances, especially the patients that are deemed to be intermediate or high-risk, based on what kind of device they bring and what kind of comorbidities the patients themselves may have. But yes, that is the opportunity now. To treat these patients in a meaningful way, with the resources, technology that are available to us now that were frankly not available two or three decades ago. And that fear that signing somebody up for a lead extraction is essentially nearly a death sentence; that fear is not only immaterial in today's day and age, but it should also not be propagated. It should not be replicated because it will only lead to delays in care. It will make patients and their clinicians hesitate and not seek formal attention and definitive treatment until sometimes it is too late—until they have evolved towards failure of multiple organs until they have significant comorbidities that may then make the surgical risk prohibitively high—not because of the surgery itself, but because of the delay and the time that it took for that decision to be made.

23:47-23:54

Liz Olson: Trudy, what do you hear from patients as the most common fears and misconceptions as they're confronting an infection?

23:55-24:44

Trudie Lobban: They are really concerned about the pacemaker being removed because they've seen it is lifesaving. So they need reassurance that it will be replaced, or whatever the treatment is. It's all the fears. The anxieties at the moment, most of them have not hardly ever heard that there may be a risk of an infection, or if it was said to them, it was as they were about to have the implant, and they don't remember it. Even if it's on their notes, they may not recall that. So it's another operation, and it is the emotional impact that it has. Also, ensuring that they are referred to a center as Miguel said, with high volume. Because if they then go on to Dr. Google and start reading all the dreadful things they can find there, they are extremely scared.

24:45-25:43

Trudie Lobban: So if they're seeing an electrophysiologist, they're seeing the right person, but they need to make sure that they've got through to the right department, someone with experience, someone with reassurance, because until that point the fact that they need a device is that they have an underlying heart condition, anyway. And now that it's being removed because it's infected having to go through everything, it is anxiety, emotionally draining, and fear of the unknown. We're not talking of thousands of patients any one time, but for each patient that has an infection, it is a real fear, a real risk, and we spend a lot of time reassuring them, educating them, making sure that

they're being supported by their medical team, and getting through it with them. And for some it has a psychological impact. So you may need to make sure they have all the support in place to come out of it on the other end feeling as good as they did when they first had the device before any infection occurred.

25:44-25:55

Liz Olson: Dr. Leal, as we're educating patients on their condition, on what's next in their journey, what have you found to be some of the most effective methods of patient education? I'm thinking, teach back maybe, multimodal.

25:56-28:01

Dr. Leal: Great question because now you're getting to that practicality, right? So how do we pass this message to patients and families? Ideally early, early into their treatment journey. So, in my experience, I've had the privilege to visit with well over 1,000 patients with this problem over the last 15 years that I've been in practice. And I've been practicing in high volume centers, both in Wisconsin and Georgia—University of Wisconsin and Emory University. And one thing that we fortunately had in common among these two sites is that there was a multidisciplinary team invested in the patient's education. As Trudie said, not too long ago, and it's such an important message, a 20- or 25- or 30-minute doctor's visit is just not enough time for this conversation to be properly undertaken. It's almost inhumane to expect a patient or a family member to remember the intricacies and details of this conversation. So the best way to educate is repetition. Repetition through visual aids that should be provided to the patient ideally before, but if not, at least after the clinical encounter. Repetition through multiple encounters. A patient that sees a physician, and then afterwards visits before the surgical date, visits with the nurse practitioner or physician assistant. They will reiterate all that message and clarify additional questions that may have arisen. They will make sure that the patient's medications are properly managed prior to the surgical date. That the patient's expectations are well understood from their end and from the end of the healthcare system as well. For instance, patients need to know how long will the surgery take, or it be expected to take? Will they be placed under general anesthesia, which they almost always are. Will they need to stay overnight, or can they count on a same day discharge, depending on what time the person who starts and ends? What's the follow up plan of care? The lead extraction is a procedure that is never contained in and of itself. It has a significant amount of time and effort devoted before, during, and after the surgery itself. So I think repetition Liz, is very important. Making sure the message is conveyed to the patient through several ways.

28:02-28:29

Dr. Leal: And that is how professional societies can also help. We need websites that are up to date, containing good visual data that patients can look. The family members can scroll up and down and clarify questions as well. And again, reiterate that message they heard from their practicing clinician, whom they visited within the clinic. So basically, we have to cater to a very diverse patient population, from the youngest to the to the most senior of our patients, and I think repetition is important.

28:30-29:49

Trudie Lobban: I totally agree with Miguel—repetition, repetition, and from numerous sources—first and foremost from the hospital, from the physicians, from the multidisciplinary team. But to gain that patient's confidence, they also need to go away and search the internet and find the same information. But not everybody is okay with the internet. Literacy, you have to pitch reading material at different stages. There also needs to be the help line which is organizations like ours offer. There needs to be more collaboration between the various organizations. Because if you go to

buy a car, you shop around. You go to different dealerships to see what is available. What you want. Healthcare isn't that much different. You want to know that you are accessing the best health care for you, as an individual. So if you hear from the doctor, if you hear from the nurse, if you go to American Heart's [Association] website and you read the same thing, if you come to Arrhythmia Alliance and you read the same thing (maybe in slightly different language, maybe it's more understandable from one than the other) or whatever, it builds your confidence. It builds your knowledge. It builds your awareness.

29:50-30:22

Trudie Lobban: And it helps you go right back to that question we had earlier that we discussed. It becomes a shared decision that we then proceed with explanting the device, etc. And the patient, of course, still anxious, who isn't anxious if they have to have an operation, but they approach it with a more confident, informed attitude. And outcomes are always better. So, it really needs to be repeated, repeated, repeated from so many different sources.

30:23-30:53

Liz Olson: Trudie Lobban, Dr. Leal, thank you so much for having this excellent conversation with me today. We can see how important it is to address the gaps and awareness, detection, and appropriate treatment, in that shared decision-making space.

30:54-31:17

Outro: This podcast is part of the AHA's National CIED Infection Initiative. This project is supported by Philips Guided Image Therapy. For the latest information about upcoming events and other resources related to this topic, please visit heart.org/treat2beatciedinfection. Thank you for listening.