[MUSIC PLAYING]

JAY WIDMER: Howdy, I'm Dr. Jay Widmer, advanced cardiology fellow at Mayo Clinic here in Rochester, Minnesota. During today's roundtable review, we'll be discussing management of pacemaker and ICD infections. I'm joined by my colleagues, Dr. Yong-Mei Cha, director of the device laboratory here at Mayo Clinic, and Dr. Rizwan Sohail, associate professor of medicine who specializes in infectious diseases. Welcome to you both.

RIZWAN SOHAIL: Thank you.

YONG-MEI CHA: Thank you.

JAY WIDMER: Let's begin. Dr. Sohail, give us a brief overview of device infections. It would appear that this is an ever-increasing entity. So how common in this, and what are some of the issues we must consider when looking at different types of device infections?

RIZWAN SOHAIL: So overall, in the last couple of decades, there has been a tremendous increase in the implantation rate of devices. And it's mostly because there's expanding indications for device placement. And we have an aging population in the United States that are candidates for devices.

And unfortunately, what was previously thought that with more experience in device implantation, and smaller size of the devices, that there should have been less infections. However, the rate of infections has increased disproportionate to the rate of implantation. And in some of the recent studies, there has been as high as 300% increase in the rate of device infections.

Now, overall for the new devices, the rate of infections remains quite low. It's less than 1%. But for revisions, and more and more patients that are getting revisions due to either upgrade of the devices from a simple pacer ICD, to resync devices, or a combination device-- or the batteries are running out and they a pack change-- the risk keeps increasing. So the second revision is higher risk than the first, and the third, and so forth.

JAY WIDMER: That's interesting. So what other factors would lead to an increased risk of infection for these devices?

RIZWAN SOHAIL: So people have tried to come up with the exact reasons why the rate of infection is increasing. And currently, it's believed that one of the key driving factors is that the type of patients who are getting the devices-- so patients are getting much older. And they have a lot more comorbid conditions. So we're implanting devices in a lot of patients with renal failure, heart failure, diabetes, immunocompromised patients, those on steroids.

So previously, the recipients were relatively younger and had less comorbid conditions. So that's one of the reasons that the device infection seems to be going at a much higher rate than implantations.

YONG-MEI CHA: Rizwan, I think that there is another component. I have noticed that as patients who receive the ICD, the bigger generator appear to have a higher infection rate than the patients who receive a pacemaker.

RIZWAN SOHAIL: Right.

JAY WIDMER: Interesting. Dr. Cha, from an operator's perspective, what factors do you see increase the rate, and what other things do you consider?

YONG-MEI CHA: Yeah, I think the main thing is, as Rizwan already mentioned about, I think re-enter the pocket is a significant factor. So overall, as you mentioned, if that's a first time new device implant the infection rate is about 1%. But if we re-enter a pocket, such as a pack change, a generator change, or need a revision-- the infection rate is higher, up to 3%. So that's a big difference.

Maybe that's related to the capsule, and that there's no vascularity or lack of vasculature. And then, maybe colonization in the device pocket is a possibility, from an infection standpoint.

RIZWAN SOHAIL: Right. So there is some data suggesting that the more number of revisions you do, the higher the risk that the pocket could get contaminated. And the more the scar tissue found, the less there's blood flow in that area. And that would also put these patients at high risk of infection with revisions, compared to the first time with the new implantation.

JAY WIDMER: Interesting, interesting. So Dr. Sohail, as we encounter these device infections, what are some of your approaches from the infectious disease standpoint, toward treating these patients?

RIZWAN SOHAIL: So you know the first issue, of course, is making the right diagnosis. So for example, patients present with pocket infection, it's relatively easy to diagnose because the redness, pain, and swelling or drainage of the pocket site. But occasionally, it can be difficult to distinguish between superficial, some redness at the incision site, versus a true pocket infection.

And in those cases, you know, one could do an ultrasound to see if there's any fluid collection or abscess formation in the pocket. And occasionally, there's new data suggesting that a PET scan could also be helpful to distinguish superficial redness or incision site reaction, versus a true pocket infection.

But a bigger diagnostic challenge that we face within device infections is the patients who have devices in place and are admitted to the hospital with fever, and have some blood cultures taken, and the blood cultures are positive.

Currently, we have millions of people living with devices. So if any of them happens to be hospitalized with fever and you have positive blood culture, what do you do with that? Does every patient with positive black culture who happens to have a device, has device infection? Or how do you distinguish that? And based on the data that we've looked at at Mayo, we've noticed that it really depends on the organism. So for Staph aureus, for example, 1/3 of the patients would have underlying device infection, even if there's an alternative focus of infection. There could be hematogenous seeding of the leads.

So for Staph aureus, we always recommend doing an echocardiogram to look at any evidence of lead infection or valve infection. For other Gram positive cocci, typically, if there is an alternative focus, you can treat the other focus. But if the bacteremia persists, or if there is no alternative focus, then you have to do an echo.

On the contrary, for Gram negative infections, the hematogenous seeding is extremely rare. So in one of the studies that we did here, we looked at Gram negative bacteremia from the urine source, or pleural source or lung and stuff, and almost had no patients with hematogenous seeding of the leads. All three patients that we noticed had Gram negative device infection had signs of infection of the pocket site. So the pocket has the source of bloodstream infection, rather than secondary seeding.

So I think this is important for people to know who are dealing with these positive blood cultures and these pacemaker devices, that they need to see what the organism is. And that would help them decide if they need to do an echocardiogram, or should they just treat the primary focus and only worry about device infection of the patient's relapse.

JAY WIDMER: Interesting. And Dr. Cha, same question, really. From an operator's perspective, how do you manage these patients, or what tips or tricks do you have for us?

YONG-MEI CHA: Yeah, that's a challenging clinical practice. Once the device is infected, and the diagnosis confirmed, then we have to remove the device, along with the leads. So as you mentioned, if it's a device a pocket infection, then we have to open the pocket, remove everything. But if the patient has a [INAUDIBLE] infection, if it's endocarditis, of course, we have to.

But if it's just bacteremia, we have to see if it's on the contrary. If not, then we have to remove. The challenge part for the lead extraction has much higher risk than with placing a pacemaker or defibrillator. And then, more often, the generator has been replaced several times, but the leads can be 10 years old, 20 years old, 30 years old. And it is very fragile with that age.

And then, we know 70% of the patient who have the device, they are 65 or older. So they have a lot of comorbidities. So that makes a further challenge to conduct the lead extraction. So we have to do that sometimes in the operating room, or our device lab, and we've very well-prepared a team, including anesthesiology, cardiovascular surgery, and even general surgeon, so on board, and then to perform the lead extraction. So complications may occur, which can be serious.

JAY WIDMER: Very complicated, must be very prepared and organized, it sounds like. Well, this has been very insightful. And just as we try to look into the future and see what might be on the cutting edge, what do you see as new developments which might help in this field either prevent or treat device infections?

YONG-MEI CHA: Yes. We do have exciting new technology coming along. One I'd like to mention is a subcutaneous defibrillator. And then that is the entire system, including generator and the lead placed under the subcutaneous skin, along the left sternal border. And the generator is on the auxillary side. So that makes a big difference, because the lead does not have to be entered into the vascular system or venous system. So that definitely will eliminate the chance of as a source of intavasculary infection. However, a subcutaneous device will carry some infection, but it's localized in the subcutaneous space.

Another new technology I'd like to mention is this leadless pacemaker. So now, currently, we have two types of leadless pacemaker we're putting in. One is called a Nanostim, one called the Micra. So these two types of tiny leadless pacemaker, they are only about 2 to 3 centimeters long. It's very, very small. And then, they're just placed where the femoral vein and is through the delivery system. And then, place them into the right ventricular apical septum.

So there is no lead. The generator can last for 10 years, as long as the current generator. And then, so hopefully, this leadless pacemaker without intravascular lead system, will eliminate or minimize the chance of infection.

JAY WIDMER: Great, great. Very, very exciting. Well, thanks, Doctors Cha and Sohail for these very important insights. Thanks to our listeners for tuning in to the Mayo Clinic Roundtable Review, at the heart.org on Medscape.