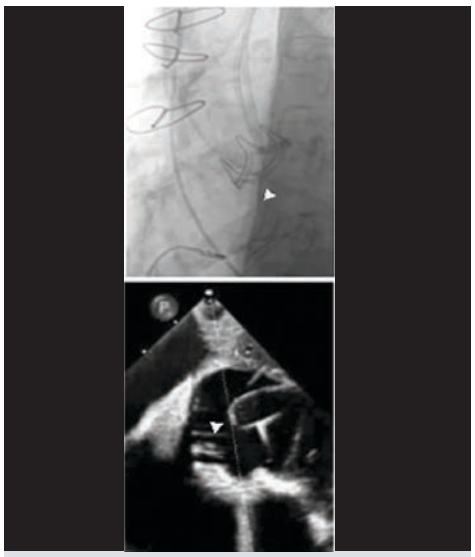
Cath Lab Digest

A product, news & clinical update for the cardiac catheterization laboratory specialist



CUTTING EDGE

A Look at the Future of Structural Intervention: The Rise of the Imaging Specialists and Cardiac Electrosurgery

CLD talks with Stephen H. Little, MD.

Baptist Health's Echocardiography and Structural Heart Symposium took place September 27-28th, in Coral Gables, Florida. *CLD* shares a discussion focusing on one of Dr. Stephen Little's presentations, "Interventional Echocardiography: Bridging the Gap Between Sonographer, Structuralist, and Surgeon." Dr. Little discusses the present and future of the structural echocardiographer on the heart team, as well as an evolving addition to the structural field, the application of percutaneous, image-guided electrosurgery.

continued on page 24

In This Issue

Best Practices Management of STEMI in the Cath Lab: Overview of the SCAI Consensus Statement 2024

Morton J. Kern, MD

page 6

Wire Entanglement to Retrieve Dislodged Stent From the Proximal RCA

Basavanna Dinesh, MD, DM, et al

page 16

Remote Cardiac Rehab: A Convenient and Effective Option Facing an Uncertain Future

Aaron Timm

page 17

STRUCTURAL HEART & EP

A Growing Concern: Patients With CIED Leads and Tricuspid Regurgitation

CLD talks with Electrophysiologist Laurence M. Epstein, MD, and Cardiac Imaging Specialist Rebecca T. Hahn, MD.

Part I. Electrophysiologist Laurence M. Epstein, MD

How should we approach the treatment of patients with cardiac implantable electronic device (CIED) leads and tricuspid regurgitation (TR)?

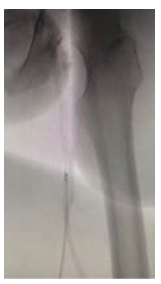
Dr. Epstein: A heart team approach is mandatory, because these patients are very complicated and the leads may or may not be contributing to the TR. Heart failure physicians can help medically manage and optimize these patients. Imagers help us understand the anatomy and the relationship of the leads to the valve, and guide any interventional procedures.

continued on page 12

THROMBECTOMY

Use of the BD® Aspirex™ Mechanical Aspiration Thrombectomy System for the Treatment of DVT and Thrombosed AV Grafts and Fistulas

CLD talks with Jeffrey E. Silpe MD, MS-HPEd.



How are you treating deep vein thrombosis (DVT)?

Over the last year or so, my practice switched from only offering treatment to patients with iliofemoral DVT to patients with both iliofemoral DVT and femoropopliteal DVT, because I believe there is both a reduction of post-thrombotic syndrome and an improvement in subject well-being with thrombectomy compared with anticoagulation alone. The Aspirex™ Mechanical Aspiration Thrombectomy System (BD) is one of my top device choices for these cases because of its ease of use.

continued on page 18

Continued from cover

A Growing Concern: Patients With CIED Leads and Tricuspid Regurgitation

CLD talks with:
Electrophysiologist Laurence M. Epstein, MD, and Cardiac Imaging Specialist Rebecca T. Hahn, MD.

Part I. Electrophysiologist Laurence M. Epstein, MD

Continued from cover

Surgeons evaluate the patient to see if an open surgical approach is warranted. Structural heart interventionalists identify whether there is a transcatheter approach to treating these valves. The heart team should also include an electrophysiologist who is comfortable with lead management.

Unfortunately, there are misconceptions when it comes to lead management. People have the idea that you can never take out a lead, it is far too dangerous, and that bad things will happen. In experienced hands, this is not the case. The risk of an extraction is significantly lower, for example, than the risk of the transcatheter valve replacement procedure.

Transcatheter tricuspid valve repairs involve either clipping the leaflets to hold them together and decrease regurgitation, or valve replacement, where a valve is placed and expanded. One option is to just clip around the lead. If the patient needs a valve replacement, it can mean jailing the lead in the valve apparatus, and this can cause lead failure by creating a fulcrum where there is pressure on the lead. If the patient develops an infection, whether it is endocarditis or a pocket infection (the most common cause of device infections), how will the lead come out once it is jailed by the device? It is a risk/risk analysis. Extracting the lead subjects the patient to the very small upfront risk of extraction, but obviates the equally complicated risks of abandoning or jailing the lead. Jailing the lead gets rid of the upfront risk of extraction, but exposes the patient to downstream risks. In any individual patient, you have to consider the patient, and the lead type and age. For example, if someone has tricuspid regurgitation three months or a year after having a pacemaker/defibrillator put in, and it looks like the lead is actually causing the TR, then it is a no-brainer that the lead has to come out. Not only are you getting rid of the risk of jailing the lead, but there is a chance the tricuspid regurgitation could improve[1] and the valve intervention is no longer necessary. One of the extraction concerns is damaging the valve and causing a flail leaflet, which means the patient may not be a candidate for the interventional procedure. Looking at the data of leads seven years old or less, there was zero incidence of this occurring.[1] Unless the patient is so old and frail that it is a palliative procedure, anyone with leads that are seven years old or younger should undergo an extraction to ascertain the impact it has on the valve and whether they even need a valve procedure post extraction. If they do need a procedure, then you have removed the lead. In people with leads older than seven years, it depends. The incidence of causing a flail leaflet was negligible until removing leads that have been in for 15 years or longer.[1]

As far as the actual risk of extraction is concerned, we did a trial several years ago called the LExICon study, evaluating real-world experience with lead extraction not only in high volume centers, but also medium and low volume centers. Looking at all-comers, the risk of a major complication was 1.4% and the risk of mortality was 0.28%.[2]

Data on lead extraction also were reported by the prospective ELECTRa multicenter analysis,[3] with a major complication rate of 1.7% and a mortality rate of 0.5%, and the retrospective GALLERY registry,[4] with a major complication rate of 2.06% and a mortality rate of 0.55%. Structural heart patients are often old and sick. These same extraction results have been demonstrated, even in the very elderly.[5,6] Yet people are very afraid of lead extraction. Part of the reason is that for many years, there have been limited options for extracting leads. Today, the combination of locking stylets, powered sheaths, and the Bridge Occlusion Balloon (Philips) has changed the face of extraction. We are much more effective at getting leads out safely. One of the major causes of mortality during extraction was the risk of tearing the SVC. It is an emergent situation where you must operate immediately. We, along with Philips, developed the Bridge Occlusion Balloon to help address this issue. The Bridge Occlusion Balloon is a large, compliant balloon that tamponades the bleeding, allowing time for surgical repair. In patients who experience SVC tears, it dramatically reduces mortality.[7] These developments make extraction safer.

Are you saying that we should never jail leads? And are you saying if possible, we should remove leads?

Dr. Epstein: There is never a "never" and never an "always". Every patient is an individual. If I am seeing a 90-year-old man with a 30-year-old lead and he has bad heart failure symptoms from his TR, the goal is to make him feel better. Jailing a lead and not subjecting this patient to the risk of an extraction makes perfect sense. The other side is a 50-year-old, who may live a very long time, is pacemaker dependent, and the lead is 2 years old. Those are the two extremes: a lead that is a year or two old, or very elderly patients with very old leads where you are palliating. The ones in the center are the ones we really need to think about and have a discussion. What is the risk of jailing the lead? Are they pacemaker dependent? What happens if the lead fails? What are alternatives for pacing? What is the risk of extraction in this patient, which is determined based on the patient, what the lead looks like on imaging, the age of the lead, and the lead model? All things being equal, leads that are less than 10 years old should come out. Leads in pacemaker-dependent patients should come out, unless there are patient-related issues like the patient age, age of the lead, and that the procedure is being performed purely for palliation.

Early on before there is scarring and fibrosis, if you remove the lead, the valve may be fine. If a lead has been there for 10 years and the leaflet has been pushed up against the septum (a common example), even if you take the lead out, the leaflet remains scarred and removing the lead doesn't fix the TR. In those cases, however, the reason to consider taking the lead out is to make the transcatheter valve procedure easier, and to avoid jailing the lead. If you jail the lead and have a pocket infection, how do you get that lead out? These patients are all high risk for open surgery and that may be your only option. In pacemaker-dependent patients, lead failures occur. Leads are complex cables of coiled wires with insulation, often surrounded by a second coil and more insulation. In the vasculature and heart, the leads are constantly flexing over and over again, and the metal filars that make up the cables can fail. If you then take a valve, jail the lead, and create a fulcrum point for the lead to bend on, it makes sense that the failure rate is going to increase.

Your sense seems to be that the structural heart teams across the U.S. may not necessarily have an EP physician who is closely involved.

Dr. Epstein: Yes. The longstanding culture has not been to involve EP. At most centers, they only call EP if the patient post TAVR has heart block and needs a pacemaker. But there is no pre involvement of electrophysiology. We need to fundamentally change that culture. EP involvement up front is in the best interest of patients and decisions should be made as a group, weighing risks of possible approaches. This is especially true for TR patients, as they often have leads and equally importantly, they may develop heart block post TTVR. Having a plan for pacing in place, prior to the procedure, is crucial.

Any final thoughts?

Dr. Epstein: My three takeaway points are that you need a team approach that includes an EP experienced in lead extraction, jailing leads is not without risk, and that lead extraction is much safer than people think. Treating these patients still needs to be a case-by-case, individualized approach. It needs to be a thoughtful decision-making process.

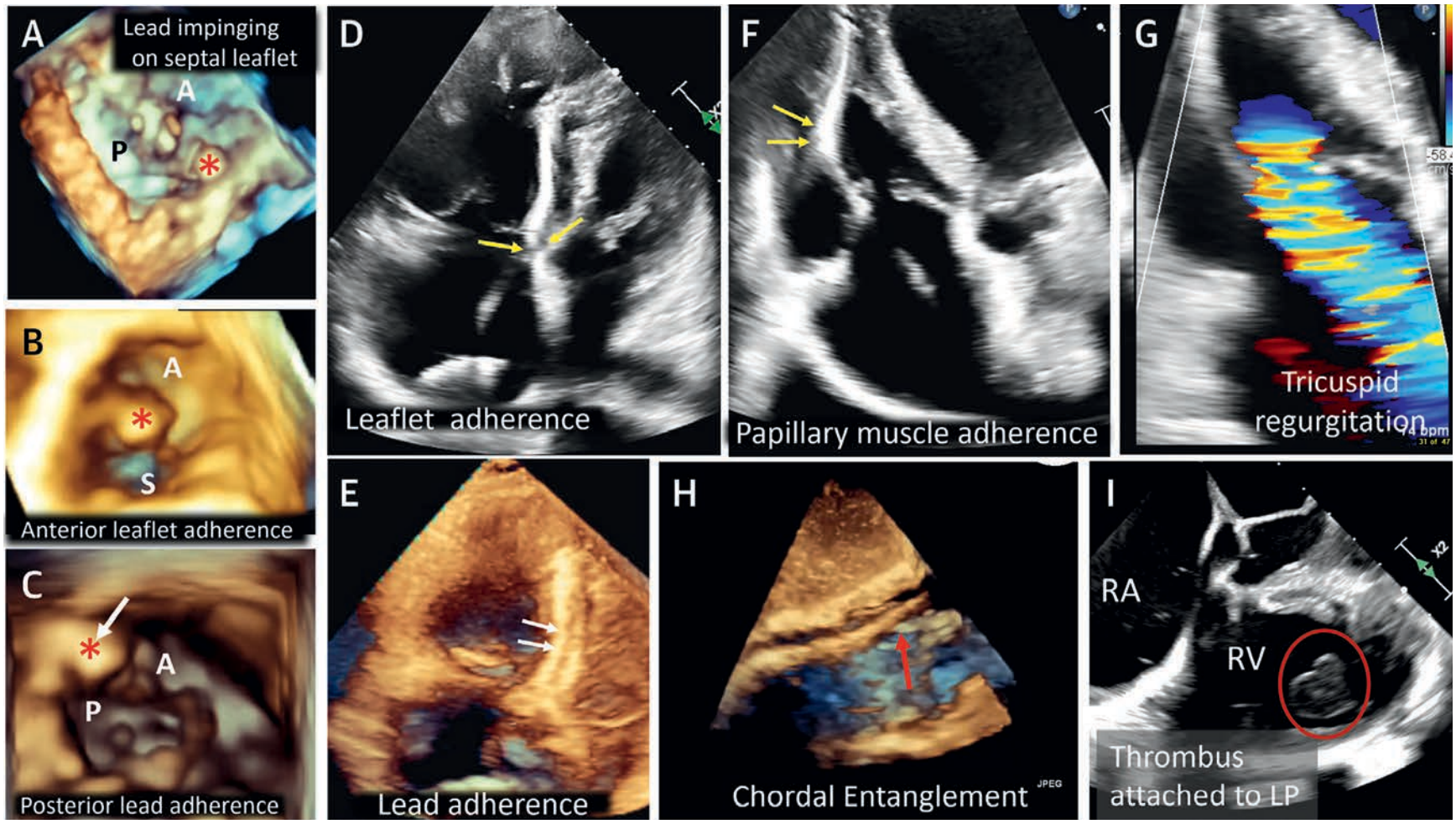


Figure. **Echocardiographic Diagnosis of the Cause of Cardiac Implantable Electronic Device Lead-Induced Tricuspid Regurgitation.**
3-Dimensional transthoracic echocardiographic reconstruction of the tricuspid valve is used to determine the location of the cardiac implantable electronic device (red asterisk) to show (A) septal leaflet impingement, (B) anterior leaflet adhesion, and (C) posterior leaflet adhesion. Apical 2-dimensional imaging windows additionally may show lead adherence (yellow arrows) on the (D and E) septal leaflet (2- and 3-dimensional, respectively) and (F) papillary muscle (color Doppler with tricuspid regurgitation in G). (H) Subcostal windows may also be diagnostic of valvular or subvalvular impingement (red arrow). (I) Thrombi on leads (red circle) may result in pulmonary hypertension and tricuspid regurgitation.

A, ¼ anterior leaflet; LP, ¼ leadless pacemaker; P, ¼ posterior leaflet; RA, ¼ right atrium; RV, ¼ right ventricle; S, ¼ septal leaflet.

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Part II. Cardiac Imaging Specialist
Rebecca T. Hahn, MD

Can you tell us about your role as an imaging specialist?

Dr. Hahn: Structural imagers are typically interventional echocardiographers. In my role, I am part of the heart team. We do all the screening on these patients, as well as intraprocedural guidance and follow-up. I have been involved in tricuspid valve interventions since 2012. Currently, the two commercially available devices are the TriClip device (Abbott) and the Evoque tricuspid valve replacement system (Edwards Lifesciences).

How often do CIED patients present with tricuspid regurgitation (TR)?

Dr. Hahn: The reported incidence has varied depending on the device and trial. For trials of the tricuspid valve transcatheter edge-to-edge repair (T-TEER) devices like TriClip, the incidence hovered around 16%. In trials of the transcatheter tricuspid valve replacement (TTVR) devices such as Evoque, the incidence of pacemaker patients presenting with severe symptomatic TR was closer to 40%, which is probably more accurate. Given the increasing longevity of our patients and the increasing number of indications for pacemakers, TR is a significant issue and a real problem. I believe more than half of the patients with pacemakers have a lead that interacts with the tricuspid valve apparatus. A recent large registry showed that the presence of the pacing lead across the tricuspid annulus is associated with a 2-fold increase in the risk of having moderate or severe TR, and that moderate or severe TR is associated with a 2-fold increase in mortality.[8] Another study confirmed that a transvenous (versus subcutaneous) implantable cardioverter-defibrillator lead is associated with a 7-fold increase in the risk of at least 1 grade worsening of TR within 6 months of implantation, in 7% of patients.[9] Clearly, all patients with a pacing lead across the tricuspid valve should be followed very closely for the development of TR. If the lead itself is the cause of the TR, consideration of transvenous lead extraction should be performed after consultation with an extraction expert and consideration of the risks and benefits.[10] However, in some patients, the risk of extraction, primarily the risk of injuring the tricuspid apparatus and worsening TR, is high, and a transcatheter tricuspid valve intervention (whether surgical or transcatheter) may be required without lead extraction. For transcatheter therapies, repair options such as T-TEER can be performed in anatomically-suitable cases (i.e., when the pacing lead is not the primary cause of the TR) with acceptable reduction in TR.[11] However, we are not always able to perform an effective T-TEER if the anatomy is unsuitable. At that point, we consider a TTVR which would entail jailing the lead, leading to concerns that prompted a Heart Valve Collaboratory meeting. Ultimately, a consensus document was created by the Heart Valve Collaboratory and our colleagues at the Heart Rhythm Society in order to bring awareness to the issues involved with treating these patients.[10] We are still learning about these patients and about the complication rates that may ensue from jailing leads with these devices. The risk of endocarditis is obviously one issue in our heart team discussions, because the electrophysiologist would be incapable of extracting a lead once it has been jailed against the native tissue with a device in place. In addition, a small registry of transcatheter valve implantation within a failed bioprosthetic tricuspid valve suggested that pacemaker dysfunction may occur in ~10% of

patients.[12] We don't yet know all the answers, but these are risks that we are concerned about.

Can you describe the tricuspid valve anatomy?

Dr. Hahn: Tricuspid valve anatomy is very complex. Only about 50% of tricuspid valves have three leaflets and the remainder can have anywhere from two to even greater than five leaflets.[12] The most common non-trileaflet morphology is a four-leaflet tricuspid valve, so it is somewhat of a misnomer. In that setting, there are a lot of chordae and we believe that the greater the number of leaflets, the greater the number of papillary muscles. Therefore, the complexity of the leaflets, the complexity of the chordal apparatus, and the complexity of the subvalvular papillary muscles are all risks for the pacemaker interacting with those parts of the anatomy. The way that the electrophysiologist places the lead may have something to do with whether or not we will eventually get interaction with any of the complex tricuspid valve apparatus. In the consensus document, we show examples of pacemakers that are adherent to papillary muscle, to the chordal apparatus, as well as to the leaflets, so it is not necessarily an isolated leaflet problem. All of those interactions will affect the way that the leaflets are able to close and therefore, may cause TR. If the lead is adherent to the leaflet and the primary cause of TR, then those patients tend not to be T-TEER candidates. However, there are patients within the trials, although we haven't evaluated this extensively, that had leads with some form of lead interaction with the tricuspid valve apparatus and they were still able to have a T-TEER device placed.

It is interesting to hear you discuss the anatomy of the tricuspid valve because so many discussions focus on the leaflets.

Dr. Hahn: In the Heart Valve Collaboratory working group meeting, there were cases presented of completely flail leaflets, not because the leaflet was injured, but because the chordae or the papillary muscle were torn. Chordal attachment and adherence is an issue that might be underappreciated. Determining the risk of lead extraction is, in large part, in the hands of the imagers. Imaging the tricuspid valve is not always easy. In the consensus document,[10] the majority of images are actually transthoracic images because the tricuspid valve and the right heart are anterior structures. Therefore, from a transesophageal view, it is a far field valve, but from a transthoracic view, it is a near field valve. Consequently, we sometimes need to evaluate by both transthoracic and transesophageal imaging in order to fully determine what is going on. Remember, this is a moving structure, a beating heart with a very small lead. That lead not infrequently moves in and out of the imaging planes. We rely quite heavily on three-dimensional imaging in order to reconstruct the images and determine exactly the location of possible interaction. Three-dimensional transesophageal imaging allows us to reconstruct those images, and then follow the course of a highly variable and curvilinear structure such as a pacemaker. Unfortunately, the temporal and spatial resolution of 3D imaging is not yet the same quality as 2D imaging. As imagers, we still run into a lot of issues when attempting to determine the exact cause of the TR when pacemakers are in place. Some of these interactions can be confirmed using computed tomography (CT) scan, because for the Evoque tricuspid valve replacement device, a pre-procedural CT scan is necessary in order to size the annulus, and determine exactly where the papillary muscles are located and the approach angle of the device. We typically have additional multimodality imaging for those patients being considered for replacement devices.

Can you share more about what is involved in the pre-procedural imaging?

Dr. Hahn: In order to determine the candidacy of patients for these devices, we do both transthoracic and transesophageal imaging. It is important to be aware of the fact that it is not just the leaflets, but the entire tricuspid valve apparatus that is involved. The pacemakers themselves can also be an issue. The paced rhythm and the location of the tip of the lead may cause some right ventricular dysfunction that leads to TR, not necessarily through interaction with the anatomy itself, but due to the location of the pacing. We've also had numerous cases of thrombus that can form on the leads and result in microthrombi into the pulmonary circulation. In that setting, right ventricular dilatation and malcoaptation of the tricuspid leaflets can occur. There are just so many things that can influence the development of TR in the setting of a pacemaker, all of which need to be considered before determining not just the most appropriate pacemaker device, but also what to do with the pacemaker. It is not just the age of the lead, but the life expectancy of the patient, and then the relative risks and benefits of each of the proposed solutions. It is the risk and benefit of transvenous lead extraction, and then the risk and benefit of jailing. This is a very nuanced discussion, and involves more than saying, it's a 2-year-old lead, let's take it out. Or it's a 15-year-old lead, let's not take it out. Those are not appropriate, comprehensive, shared decision-making discussions. It has to involve all of the factors that we consider when we have a patient with a lead.

Imaging is necessary to steer the ship in these discussions.

Dr. Hahn: Imaging is essential as we make a shared decision with the patient about how best to manage their lead. Three-dimensional advanced imaging is not always performed in all centers. This is, to me, one of the most important points to make. For Dr. Epstein, the point is to please involve the electrophysiologist, and there is no question that this is absolutely essential. But the role of the imager comes even before the role of an electrophysiologist. It comes before the role of an interventionalist or structuralist. Imagers are, in a sense, gatekeepers, because we have to not only make the diagnosis of severe symptomatic TR, but we also need to understand the etiology of that regurgitation. There are a variety of different anatomies and pathologies that may not be appropriate for each of these different devices under consideration. We do depend on our clinicians as well as heart failure experts to bring symptomatic patients to our attention, in what they believe to be in heart failure or right heart failure. At that point, the team relies heavily on the imager to determine the etiological severity and the appropriateness of various treatment courses, which could actually be medical therapy. In patients with heart failure with preserved ejection fraction, echocardiographic data can determine whether the patient would benefit from an SGLT2 inhibitor. We've had patients almost completely resolve their TR just from appropriate treatment of left heart disease. It's amazing. Imaging tells us so much about this disease process and all valvular heart disease processes, and it is integral to the appropriate management of these patients. Advanced imagers are essential to help make these decisions.

Any final thoughts?

Dr. Hahn: We are getting elderly patients with leads that have been in place from somewhere around 7 to 10 years up to 20 years. This is speaking from personal experience, so it is not anywhere in the literature that I can find, but unless there is an immediate determination of lead interaction with the tricuspid valve, it takes about 5-7 years of lead dwell time for scarring and adhesions of the pacing lead to the valve apparatus, to result in severe, symptomatic TR. With the delay in diagnosis of severe TR, the resulting medical management attempts and eventual progression of the disease, patients come to our attention late, having developed edema, ascites, and evidence of low cardiac output. At that point, extraction is a risk/benefit determination. Every single patient has to be evaluated in the context of their own medical co-morbidities, symptoms, and expectations of therapy. You cannot make decisions based on single parameters — these are all very nuanced decisions and deserve an in-depth shared decision-making discussion. ■

This article is sponsored by Philips.

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