

# Cath Lab Digest

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



## OUTPATIENT CARE

### Meeting Community Need: First, an ASC, Then the New Hospital Comes Later

CLD talks with Eunmee Shim, President, Adventist HealthCare Fort Washington Medical Center, Fort Washington, Maryland.

### Can you tell us about Adventist HealthCare and Fort Washington Medical Center?

Adventist HealthCare is one of the longest-serving health systems in the Washington, DC, region, serving our communities for almost 120 years. Based in Gaithersburg, Maryland, Adventist HealthCare consists of three acute care hospitals (Fort Washington Medical Center, Shady Grove Medical Center, and White Oak Medical Center), Adventist HealthCare Rehabilitation Hospital, outpatient rehab clinics, imaging centers, cancer centers and a variety of physician practice locations. Adventist HealthCare also manages Howard University Hospital in Washington, DC.

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## THROMBECTOMY

### Computer Assisted Vacuum Thrombectomy (CAVT) for Pulmonary Embolism: Penumbra's Lightning Flash 2.0™



CLD talks with Rohit Bhatheja, MD, MBA, FACC, FSCAI.

### For a patient receiving endovascular treatment for a pulmonary embolism (PE), what does the pathway prior to their intervention look like?

Endovascular treatment of PE is reserved for those patients who are intermediate or high risk, which means they have more than just a diagnosis of PE. These patients are having significant symptoms and their PE is affecting their right heart. Typically, these patients are either coming to us directly from the emergency department (ED) or from the intensive care unit (ICU) when they experience worsening symptoms. We then consult with the ICU team (dual agreement) in the hospital to risk stratify and evaluate their candidacy for a catheter-directed intervention.

### How does PE affect the heart?

PE is a spectrum of venous thromboembolism in which typically the clotting happens in the venous system in the legs or sometimes in the upper extremities, and then migrates to the lung arteries. The thrombus can vary in size and morphology. When the thrombus is lodged in the pulmonary circulation, it can begin to cause strain on the right side of the heart that connects directly with the lung system. This is called right ventricular (RV) strain.

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## CRT CASE COMPETITION

### Finalists From CRT's 2024 Nurses and Technologists Interesting Cases Competition

The Cardiovascular Research Technologies (CRT) meeting was held March 9-12 in Washington, D.C.



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# Computer Assisted Vacuum Thrombectomy (CAVT) for Pulmonary Embolism: Penumbra's Lightning Flash 2.0™

CLD talks with Rohit Bhatheja, MD, MBA, FACC, FSCAI.

RV strain can lead to low oxygenation (hypoxemia), low blood pressure, (hypotension), and in some instances, cardiogenic shock. There are various spectrums of PE presentation, from the least sick population in which the patient will just have symptoms of chest pain, all the way to shortness of breath, coughing up blood, hypoxemia, tachycardia, and collapse. The spectrum is quite variable.

Imaging will show enlargement of the RV or RV hypokinesis, which is poor function of the heart, with accompanying electrocardiogram changes or elevation of blood biomarkers that suggest necrosis in the heart. If this situation remains uncorrected, patients will spiral into a cascade where hypotension may lead into the disastrous consequence of shock. One of our roles as interventionalists is to stop this cascade and resolve the right heart strain. Quick use of a mechanical thrombectomy systems can reduce the likelihood of this cascade. We can change their course from a slippery downslope to stability, and, often in our experience, then discharge them without any major drugs except blood thinners.

## Can you tell us about pulmonary embolism response teams (PERTs)?

PERT is integral to most successful pulmonary embolism programs. People may or may not use the term "PERT," but basically it is a team comprised of interventionalists (who could be cardiologists or radiologists), cardiac surgeons, and vascular surgeons, who all have tremendous interest and expertise in interventional management of PE. In addition, the team includes ED and critical care physicians who actually see PE patients in their initial presentation, and make a combined decision about the patient's treatment modality for acute care. Once the decision has been made and the patient is on the path for improvement, then the PERT will engage other specialties like hematology and oncology to determine if there was a cause for the PE.

PERT also involves our pulmonary colleagues to determine if the patient requires an evaluation for lung function and then further outpatient treatment to make sure the pulmonary blood flow is normal. While structures and approaches vary by institution, PE response teams activations may summon these specialists simultaneously, allowing them to work in tandem. Utilizing a multidisciplinary approach allows for a comprehensive plan of care for these patients. Usually there is one individual(s) who starts the PE program and gradually the program builds on its own success, as we did here in my institution where I initially started the program.

In our institution, mostly it is a combination of interventional cardiologists and interventional radiologists that do the interventional procedures. We have a very good working relationship across the entirety of the workforce, including hospitalists, critical care, and ED physicians. If they need help from cardiologists with an expertise in pulmonary embolism, we will respond to them.

## When you do have a thrombectomy case for PE, what are the clinical endpoints you are looking for?

Clinical endpoints for a PE thrombectomy are twofold: intraprocedural and post procedural.

The intraprocedural endpoints center around an improved clinical outcome. Some patients come in with low blood pressure and their pressure improves. Some patients come in hypoxemic and their oxygenation gets better. In most patients, we will measure their pulmonary artery pressures, and after doing adequate thrombectomy, sometimes their pulmonary artery pressures will decrease back to more normal levels. In some instances, the clot burden improves significantly angiographically, which means an increased perfusion of blood into the distal pulmonary circuit. Improved distal pulmonary perfusion, reduced PA pressures, and improved oxygenation and blood pressure are good markers for procedural success.

Once post procedure, within 48 hours we look for an improvement in right ventricular function and size, which has been the primary outcome for all the clinical studies. If the RV to left ventricular (LV) ratio improves after the procedure, it means the right ventricle is experiencing less stress. I personally do not recommend computed tomographyangiography (CTA) right after the procedure. Alternatively, I recommend around 8-12 weeks post procedure to get a new baseline (which is usually normal at that time).

Finally, pre-discharge, we look for the patient to be at a normal blood pressure without tachycardia and on anticoagulation without oxygen to be sent home.

## Why is the focus during the procedure to offload the right ventricle by establishing perfusion?

It is very important to focus on the RV as a marker for PE diagnosis and treatment success and not be enamored just by large clot pictures. Clinical studies have shown that in PE, it is the RV that is affected and that decides the outcome of the patient, not necessarily the amount or the location of the clot. Over the past 10 years or more, the marker for success/primary outcome for clinical studies has been the



**Figure 1.** Penumbra team members with Dr. Bhatheja (center) from the world's first-ever Lightning Flash 2.0 case.

RV/LV ratio, so we are really looking for the RV/LV ratio to improve. In acute PE, the RV enlarges and may become balloon-sized, hypokinetic, and unable to function, leading to hypotension. However, once we do adequate thrombectomy, the RV is able to generate the pressure to improve pulmonary perfusion. At 48 hours, when we do an echocardiogram, we typically see that the RV has not only improved in function, but improved in size. Overall, research needs to continue in order to determine if RV/LV ratio is the correct endpoint to monitor or we need to look into better markers for RV function, and only future clinical trials will inform us about what matters most in these patients. For example, I was part of a study that was presented at the 2024 American College of Cardiology Scientific Sessions looking at novel metabolomics/blood markers in acute PE.

## What are some of the more recent advancements for the treatment of pulmonary embolism?

The advances are twofold. One is pharmacological. For the past several years, we have had good, predictable, injectable, parenteral anticoagulation strategies. In extreme situations where the patient is in cardiogenic shock and there is no other treatment availability, we have the ability to use thrombolytics, which have been shown in certain studies to help patients with acute PE. And now we have oral anticoagulant drugs that are predictably effective in reducing clot recurrence.

However, the greatest advancement over the past several years has been in the device therapy arm of percutaneous PE intervention. We can perform almost instant treatment of PE with very quick recovery of the right ventricle, sometimes without giving thrombolytic drugs that can cause a bleeding risk. The percutaneous options include the newest generation aspiration thrombectomy and computer assisted vacuum thrombectomy (CAVT), in which the concept is fairly simple.

## Can you describe computer assisted vacuum thrombectomy further?

## Penumbra's Lightning Flash 2.0 is currently the only CAVT technology available that allows us to do thrombectomy from the pulmonary arteries utilizing clot detection algorithms that can differentiate between clot and patent flow.

Penumbra's Lightning Flash 2.0 is currently the only CAVT technology available that allows us to do thrombectomy from the pulmonary arteries utilizing clot detection algorithms that can differentiate between clot and patent flow.

It gives us the advantage of the potential to reduce significant blood loss since we are no longer doing this procedure blindly. You can work with the software, which is designed to pull out clot with reduced estimated blood loss (EBL), which is a significant advancement over any other available thrombectomy devices on the market. The device is not just for the pulmonary circuit, but also has been cleared for the use of venous thrombus removal. There are few other devices on the market, but they are mostly a tube and suction system without any smart circuit or intelligent technology, and are not CAVT.

### Let's say you are in a case and planning on doing CAVT. What does that workflow look like?

We usually enter the venous system either through the neck or from the groin, and move through the venous circuit through the heart into the pulmonary artery. Based on the patient's CT scan and the pulmonary angiogram in the cath lab, we are able to determine the clot location and quantify the clot burden. The goal is to remove the clot from the pulmonary artery vasculature with safety, speed, and simplicity.

Lightning Flash 2.0 is extremely trackable in my experience. Even in the toughest of the cases where the right ventricle is severely enlarged and the pulmonary artery pressures are high, we have

been able to seamlessly track this device without much resistance into the pulmonary circuit. With the help of the Lightning Flash 2.0's pressure sensors and flow-based microprocessor algorithms, we are given visual as well as auditory feedback that helps us discern between blood clot and blood flow. When the computer software detects that the device is not in a clot, it is designed to adjust to minimize blood loss. It is a unique feature of the Lightning Flash technologies that help preserve access to the pulmonary circuit without the device having to repeatedly go in and out.

With Lightning Flash 2.0, it was possible for us to finish the entire case in the left and right pulmonary arteries without even removing the device from the body, because of its torqueability and the unique ability of its computer-guided algorithm.

### Could you talk more about the device trackability?

First, of course, you need good venous access to make sure you are in a good position in the vein. The catheter should be flexible, but also stiff enough so it doesn't bend and cause collapse of the tubes during the thrombectomy. Lightning Flash 2.0 is made with a special hypotube technology that provides an inner diameter similar to a large-bore catheter. At the same time, it is lubricious and, in my experience, will move without kinking through tortuous anatomy, from the cava into the right atrium, to the RV, into the pulmonary circuit.

Penumbra's Lightning Flash 2.0 catheter technology has a comparable inner diameter to large-bore catheters, but has a lower profile to help us reach the difficult-to-place areas. The catheter has an atraumatic tip design, so even if you are going deeper into the pulmonary circuit, I have experienced good outcomes. I have been able to track it down deeper into the pulmonary circuit and still obtain a good result, even in the most difficult cases.

The Lightning Flash 2.0 gives you lubricious trackability, low kinking, and a large lumen inner diameter, despite it being not a large-bore catheter — all great markers for thrombectomy success.

### How has your use of the Lightning Flash affected your patient outcomes?

We have come a long way from patients staying in the hospital for 3 to 7 days after treatment with anticoagulation or with catheter-directed thrombolysis.

Patients would stay in the ICU for 6 to 24 hours, and then we would have to bring them back for a re-angiogram and to remeasure their pressures.

Now we can offer an almost instantaneous on-the-table therapy for all PE patients. It is a complete change from where we began in our journey of interventional management for PE. In my institution, many of these patients, if they are doing well clinically, can be rapidly stepped down from the ICU to PACU, their door-to-home time has also been significantly reduced, and we have seen they are early to ambulate.

A shorter length of stay means they will have less chance of hospital-acquired infections, fewer phlebotomies, and a lower complication rate. They are discharged on newer oral anticoagulants that work well with CAVT. You can introduce these drugs almost in the same day of the procedure, so often we are able to send the patient home within 24 to 48 hours of the procedure. It has been a game-changer in what we do for patients with PE.

### Any final thoughts?

PE management has changed significantly from about two decades ago when people were just managing PE based mostly on their own experience. Now, we have a much better idea about how to risk-stratify PE patients before we even talk about therapies. We always first risk-stratify the patient into a low risk versus non-low risk patient. If they are non-low risk patient, we then classify them into intermediate, intermediate-high risk, or high risk, and then incorporate other scoring methodologies like the simplified Pulmonary Embolism Severity Index (sPESI) score and European Society of Cardiology (ESC) classification. It allows us to discuss with the team an optimal strategy based on evidence and not just anecdotes, and then share that with the patient and their family.

Historically, PE has meant acutely sick patients with a high risk of mortality. Today that story has changed for the better. We can treat PE: we have data we can trust and there are delivery models, physician teams, and devices to deliver therapy to these patients. ■

Interview sponsored by Penumbra, Inc. Dr. Rohit Bhatheja is a consultant for Penumbra, Inc.

Procedural and operative techniques and considerations are illustrative examples from physician experience. Physicians' treatment and technique decisions will vary based on their medical judgment. The clinical results presented herein are for informational purposes only, and may not be predictive for all patients. Individual results may vary depending on patient-specific attributes and other factors.

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View Dr. Rohit Bhatheja's interview online by scanning the QR code:



### Rohit Bhatheja, MD, MBA, FACC, FSCAI

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