The lineup at CRT is once again complete with expert faculty, cutting-edge sessions and innovative technology. To help attendees plan their time and find topics of interest at this year’s boutique meeting, the sessions are divided into six tracks: Coronary, CRT Valve and Structural Heart, CRT Endovascular, Technology and Innovation, Atherosclerosis and Research, and Nurses and Technologists. With new offerings and in-depth research on critical limb ischemia, percutaneous coronary intervention and more, CRT 2018 will offer attendees the resources and skills to impact their practice. This robust conference will unite physicians, regulators, fellows and industry members at the Omni Shoreham Hotel in Washington, DC, from Saturday, March 3, to Tuesday, March 6.

“If you’re an interventional cardiologist, this meeting is a must for you,” said CRT Course Chairman Ron Waksman, MD. “It gives you everything you need to impact your practice. In addition, this year’s meeting is the first time in the whole 40 years of percutaneous coronary intervention that we’ll have a live case operated entirely by women. This has never been done before in any live case demonstration, and we are very proud of it.”

Here’s a glimpse at what you can expect at CRT 2018:

- First-ever live case operated entirely by women
- Live cases from around the world
- Highly anticipated low-risk TAVR trial interim results
- President Obama, the Honorable Donna F. Edwards and Dolvett Quince delivering keynote addresses
- Innovations in interventional cardiology technology
- FDA Town Hall
- LAA closure workshop
- Abstract Café and Exhibitor Reception
- Women in interventional cardiology roundtable
- Bioabsorbable stent discussions
- FFR and iFR coronary physiology workshops
- International consensus on switching P2Y12 inhibitors during dual antiplatelet therapy
- ORBITA trial results discussion

Cite as: Waksman R. President Obama to speak at CRT 2018. J Am Coll Cardiol. 2018;71(12).
Post-LAA closure therapy faces debate; five-year data reveal Boston Scientific Watchman device is still effective

Five-year PROTECT AF and PREVAIL data revealed that the Boston Scientific Watchman device for left atrial appendage (LAA) closure is still a safe and effective alternative to long-term warfarin therapy for non-valvular atrial fibrillation (AF) patients. But the adoption of LAA closure has been slower than what people thought it would be, said Michael Rinaldi, MD.

“There are a lot of patients who could potentially benefit from this technology that aren’t receiving it,” he said. “Primarily, it’s due to lack of general knowledge that the therapy exists in the internal medicine and cardiology community. We need to do a better job of getting the word out. Strokes are bad, and the best treatment for stroke is prevention.”

The LAA Closure Workshop on Saturday, March 3, at CRT 2018 aims to bring awareness to the Watchman device and discuss the debate of post-implant anticoagulation therapy.

Patients who meet the U.S. FDA label for Watchman typically have bleeding problems, and the label requires patients to take oral anticoagulation therapy for six weeks after implant.

“Many of those patients can’t take oral anticoagulation therapy long- or short-term, so the Watchman is associated with exposure to a blood thinner and bleeding complications,” said Dr. Rinaldi, an interventional cardiologist at Carolinas Medical Center in Charlotte, North Carolina. “A post-op analysis of the PROTECT AF data showed that whether the patients achieved therapeutic anticoagulation with warfarin after implant or not, they had the same outcomes, which were good.”

Outside of the U.S., patients are being treated with antiplatelet therapy instead of oral anticoagulation, but the U.S. is subject to a national coverage decision and can’t offer that option.

To address that, the ASAP 2 study is currently enrolling patients with a contraindication to warfarin treatment. In that study, patients are assigned to either receive a Watchman implant with dual antiplatelet therapy but without a warfarin bridge or not receive an implant in an effort to see if antiplatelet therapy alone is safe and effective.

In addition to post-LAA closure therapies, Dr. Rinaldi also will address how to efficiently screen patients and assess whether their anatomy is conducive to LAA occlusion and determine the appropriate device. Traditionally, screening has been done with transesophageal echocardiography (TEE), but Dr. Rinaldi said there are limitations to TEE.

“We’ve found, particularly in TAVR, which started out with echo, that CTA was superior in terms of really defining anatomy and picking the best device to match the anatomy,” he said. “We’ve taken this concept and applied it to the LAA space and have moved entirely to screening patients with CTA.”

Dr. Rinaldi said computed tomography angiography (CTA) has better anatomy resolution and better three-dimensionality. Additionally, it’s quicker, the patient doesn’t need any sedation, it’s cheaper and more efficient and it has better resolution. On the downside, it involves some contrast. It’s not the right tool for all patients with chronic kidney disease and it involves some radiation. However, the amount of radiation required is pretty low and less than would be associated with coronary intervention.

“Systems should consider CTA rather than TEE for assessment given the inherited advantages,” he said. “We believe it will eventually become the standard way people assess. We believe that’s the future.”

ORBITA reveals PCI is no better at reducing angina symptoms than placebo procedure

Results of a blinded, multicenter randomized trial revealed percutaneous coronary intervention (PCI) does not result in a statistically significant increase in exercise time compared with a placebo procedure in patients with medically treated angina and severe coronary stenosis. The Objective Randomised Blinded Investigation with optimal medical Therapy of Angioplasty (ORBITA) results were presented at TCT 2017 in November.

The study compared how effective medical therapy is versus stent therapy using angiographic guidance. Although implanting a stent into a patient already on medical therapy improves exercise time over baseline compared to those with just medical therapy, the prespecified endpoint was not met.

Many interventional cardiologists were discouraged by the results, but study supervisor Justin Davies, MD, PhD, remains hopeful.

“This study is a reminder of the fact that you need to use medical therapy and intervention in the appropriate way, and no patient is potentially suitable for medical therapy or only suitable for PCI,” said Dr. Davies, a consultant interventional cardiologist at Hammersmith Hospital, part of Imperial College London. “These are both options that we have to treat patients, and we need to use the right therapy for the right patients.”

The study—conducted by the Imperial College London—enrolled 230 patients with ischemic symptoms, and 200 patients underwent randomization. Of those participants, 105 patients were assigned PCI and 95 were assigned the placebo procedure. Following a six-week follow-up, there was no significant difference in the primary endpoint of exercise time increment between the two groups (PCI minus placebo 16.6%, 95 percent CI -8.9 to 42.0, p=0.20).

Dr. Davies said the study reveals two things: First, interventional cardiologists can’t rely purely on the angiogram, even if the artery looks like it has a tight narrowing in it. Second, interventional cardiologists need to fall back to pressure wire techniques to guide them more carefully in these situations.

He suspects it will be discussed thoroughly at CRT 2018 as many physicians will perceive the results as a worry for the future of coronary intervention with angioplasty, which he doesn’t see.

“I think people will be worried about the potential implication on their practice, but I honestly think, if you’re doing the right practice—you’re treating patients, not treating arteries—then you don’t have anything to worry about,” Dr. Davies said. “Stenting is an established technique for opening up an artery, clearly beneficial in myocardial infarction, clearly beneficial in acute coronary syndrome and clearly beneficial in patients who can’t tolerate drug therapies as well.”

Dr. Davies looks forward to the results of ISCHAEMIA and is currently working on developing ORBITA 2 with the team at Imperial College, which will compare the benefits of stenting in patients off medications.

“That would give you a real measure as to how effective this stenting is,” he said. “I suspect it’s very effective, but again, it wouldn’t be polluted with the effect of medical therapy, which makes it difficult to interpret the actual improvement of medical therapy over and above the placebo effect of stenting.”
Interim low-risk TAVR trial results will be revealed at CRT 2018

Results of a MedStar Washington Hospital Center low-risk transcatheter aortic valve replacement (TAVR) study will be revealed for the first time at CRT 2018 during a late-breaking trial session. The study compares outcomes of surgical aortic valve replacement (SAVR) and TAVR in low-risk patients with severe aortic stenosis to determine whether TAVR can be expanded from its current indications. TAVR—now established as a mature technology—is currently approved for high-risk and intermediate-risk patients. MedStar is the first group to receive an investigational drug exemption from the U.S. FDA to see if TAVR is noninferior to surgery for low-risk patients. Results of approximately 125 patients out of the 200 patients enrolled who completed the endpoint will be shared. Following MedStar’s study, Medtronic and Edwards Lifesciences started their own randomized studies examining the same question.

“These interim results would give us the first glimpse into what we should expect from the overall low-risk study that everybody is anticipating,” said Ron Waksman, MD, CRT Course Chairman. “It’s going to take another year and a half before the companies will report their own trials. It’s going to give us some indication whether the low-risk indication would be expanded also for TAVR. That’s why we are so excited and that’s why there is a lot of anticipation for the study results.”

Ten centers are participating in the study, and each operator is allowed to choose any TAVR device approved for the other two indications. “The issue is there is a very high bar because surgery results for low-risk patients are very good with very little morbidity and mortality,” Dr. Waksman said. “I think the bar for intervention in this cohort of patients is much higher than what the other studies have been compared to surgery.”

Physiology workshop will examine differences between indices

MORTON KERN, MD, MSCAI, HOPES attendees who join the FFR/iFR Coronary Physiology workshop will realize that the differences among fractional flow reserve (FFR), instant wave-free ratio (iFR), coronary flow reserve (CFR) and diastolic pressure to aortic pressure ratio (Pd/Pa) aren’t as vast as one may think.

“If you want to use a resting index and don’t have iFR, you can use diastolic Pd/Pa and apply FFR in subsets, in which the iFR studies have not been released,” said Dr. Kern, co-moderator of the Saturday, March 3, workshop.

However, there is some confusion on when and how to use them. The session will review the underpinnings of each index, including the mechanisms and rationale between the hyperemic and non-hyperemic translesional pressure indices in an effort to reduce that confusion.

“The first session has to deal with understanding the differences between pressure and flow,” Dr. Kern said. “What this session will do is set the stage for understanding where FFR comes from and what it needs. It also will put iFR into perspective—where it comes from, what it means and how it relates to FFR. Then we’ll talk about CFR, which was the beginning before FFR was even around.”

FFR is now a standard for lesion assessment when no other data outside the catheterization lab are available or when an operator’s trust in that data is poor. iFR is currently competing for a standard, but it only has two studies with low-risk patients and only a few years of data, whereas FFR has nearly 20 years of data. Pd/Pa is now a competitive index for iFR, and the next milestone will be a diastolic Pd/Pa, which will be the same as iFR, said Dr. Kern, member of the division of cardiology and professor of medicine at the University of California, Irvine.

The workshop also will dive into the interventional application of the indices, including FFR and iFR pressure pullback in patients with stenosis. “It’s the pullback using iFR which is perhaps more interesting in terms of being quicker, easier and not having to deal with interaction of lesions as you pull back,” Dr. Kern said. “However, it’s unproven at this time whether it will be a benefit or not. The assessment of serial lesions is also done with this methodology. And if it’s easier and quicker and equally accurate to FFR, it will probably replace it.”

The third section will allow companies entering the device market to highlight interesting aspects of their wire. “There also will be a presentation on the angiographic measurement of FFR without wire pressure,” Dr. Kern said. “It’s a three-dimensional reconstruction applying computational fluid dynamics to the artery images and then producing an FFR number, which is supposed to be close to the measured FFR number.”

Dr. Kern suggests attending the “The Pressure Flow Relationship, CFR, FFR and iFR Underpinnings,” “Image Based FFR-Angiography: The Tech Concept and Clinical Validation in CAD Patients” and ending the day with the parade of new FFR systems.
Session will help women build network of mentors

By only representing 4 percent of all interventional cardiologists, women face adversity in the workplace with fewer role models, larger pay gaps and historically fewer promotions.

But women are starting to break through some of those barriers thanks in part to inspiring and powerful women and programs that encourage them to take the reins.

To exemplify those successes and efforts, CRT will host its first live case operated entirely by women. The case is an extension of this year’s Abbott-sponsored Women in Interventional Cardiology Roundtable that will address women’s workplace issues and provide a lively interaction with the women in the audience. During the Monday, March 5, session, several women will share cases they’re proud of—which allows for recognition and professional development—while others will offer advice and personal stories of triumph.

“We wanted to give women an opportunity to talk with other interventional cardiologists and mentors to bond and create a network of mentorship,” said Cindy Grines, MD, FACC, FSCAI, a moderator of the Women in Interventional Cardiology session, was once told she was acting like a “bull in a china shop” when she was tasked with creating an acute interventional STEMI program. Although the program became successful and busy with transfers, if a man would have been heading the department, she said, he would have likely been described as “hardworking, visionary and a brilliant strategist.”

That’s exactly the kind of language and attitude this program aims to fight.

“We need to have more women role models and more women in leadership positions with high visibility,” said Dr. Grines, medical school chair of cardiology at the Zucker School of Medicine at Northwell Hofstra University. “We should have medical students and internal medicine residents rotate in cardiology and spend a few days in the cath lab. Many women don’t even think of interventional cardiology since they have no exposure.”

The session will address how to increase women in leadership positions for professional societies and how to encourage women to become interventional cardiologists. A roundtable will follow addressing how to become a successful interventional cardiologist.

“Work harder than your colleagues, say ‘yes’ to extra work, seize any potential research or speaking opportunity,” Dr. Grines said. “But importantly, develop emotional intelligence and friendships with colleagues because at the end of the day success is 80 percent interpersonal relationships.”

CLOSING THE HEALTH-care disparities gap starts by examining diet and nutrition, according to Kim Williams, MD, MACC. Dr. Williams will be co-moderating the 2018 Disparities Panel with Wayne Batchelor, MD, MHS.

“Nutrition is one of the fundamental differences that result in disparities in cardiovascular outcomes for African-Americans and Asian-Americans,” said Dr. Williams, a vegan cardiologist at Rush University Medical Center. The vast majority of cardiovascular disease—including stroke, heart attack and heart failure—is rooted in nutrition.”

The panel will address nutrition, hypertension, lipid management and genetic differences in ethnicities on the evening of Sunday, March 4. The Honorable Donna F. Edwards will deliver the keynote address, “Disparities & Closing the Gap,” during the session, speaking about her experiences and advocacy to reduce disparities in health care.

Batchelor, an interventional cardiologist with Southern Medical Group, PA, is scheduled to give the “Changing Nutrition to Decrease Disparities” presentation about how certain ethnic foods and diets impact the risk for cardiovascular disease, particularly the Western diet, which is packed full of processed meats, salty snacks, sweets and soft drinks.

In addition to dietary concerns and cardiovascular disease, millions of more Americans were defined as hypertensive on Nov. 13. The new hypertension guidelines, released at the American Heart Association Scientific Sessions, now consider a systolic/diastolic reading of 130/80 mm Hg to be hypertensive, down from the old standard, 140/90. The American Heart Association and the American College of Cardiology formulated the guidelines.

Dr. Williams, who was on the blood pressure guidelines committee, will address ethnicity and the new guidelines during this session, speaking to the new targets and differences in management and hypertension in Hispanics and African-Americans.

“African-Americans are more hypertension prone and have more overall renal failure, heart attack, stroke and heart failure with a higher mortality,” Dr. Williams said. “It’s great to have new therapies, but we need to address how they are applied to African-Americans and how they should be preceded by wholesale lifestyle changes.”

Finally, the session will explore the genetic ethnic differences that need to be taken into account during lipid management in the session “Dyslipidemia Management in At-Risk Populations.”

Disparities panel will address nutrition, new hypertension guidelines
CRT to host first live case operated entirely by women

New this year, CRT will feature an all-women live case from Mount Sinai Medical Center in New York. Everyone from the interventional cardiologists to the commentators will be female, which reflects CRT’s emphasis on women in interventional cardiology. CRT Times caught up with Annapoorna S. Kini, MD, MRCP, FACC, director of the Cardiac Catheterization Lab at Mount Sinai Hospital and one of the women who will be performing the case.

What was the impetus for a case being operated by only women?

There are very few women in the field of interventional cardiology. Watching women perform a live coronary interventional case will spark younger women fellows to follow suit and draw inspiration from the leading female interventional cardiologists as they pursue their dream to be the best in the field.

What are some challenges or obstacles women face in interventional cardiology?

Interventional cardiology remains a heavily male-dominated subspecialty—relatively few women choose to become interventional cardiologists even today. While the subspecialty does have some unique challenges including radiation exposure and long hours, some gender stereotypes regarding the profession as a “male job” might discourage young women from pursuing their dream. Many patients and even referring doctors do not prefer a woman interventionalist performing a procedure. This could be challenging, but we are trying to make a difference and we are hopeful that women interventionalists will be given the chance to shine in this field.

How does this live case show a triumph for women?

We have to be competent and better than our male counterparts to do a live case. Both Drs. Waksman and Sharma are constant supporters of women in this field and very keen in giving us this opportunity. This will be the first live case ever to be performed by an all-women team. We want more leaders in this field to support women in this endeavor.

How does this live case speak to the future of women in interventional cardiology and the current work environment?

I believe it is possible for a woman to be a great physician, wife and mother; however, it might be quite challenging, especially while raising small children during medical school or residency. My advice would be to try to get all the help you can, including immediate and extended family and friends. Having clear priorities and understanding what really matters also will help to focus on important things. Looking for work-family balance will not stop with children getting older; it’s a nonstop process, and I believe everyone can master it. Since life is always changing, the balance will be changing, too, and it’s important to note what’s working and what’s not. Work and family life don’t have to be separated; they can be connected in many different ways to enrich each other. While balancing work and family life will always require attention, I believe that women can be successful interventionalists and bring their unique perspective to patient care to save more lives. Sharing work news with children, taking them occasionally to work, business trips and conferences might help them find their own path in life.

‘Watching women perform a live coronary interventional case will spark younger women fellows to follow suit and draw inspiration from the leading female interventional cardiologists as they pursue their dream to be the best in the field.”

- Annapoorna S. Kini, MD, MRCP, FACC
LOTUS VALVE SUPERIOR TO EVOLUT R / COREVALVE
Primary effectiveness endpoint (1 year): Composite of all-cause mortality, disabling stroke, moderate or greater PVL. LOTUS Valve = 15.8% vs. Evolut R / CoreValve Platform = 26.0%. Superiority \( P < 0.001 \).

LOTUS VALVE NON-INFERIOR TO EVOLUT R / COREVALVE
Primary safety endpoint (30 days): Composite of all-cause mortality, stroke, life-threatening and major bleeding events, stage 2/3 kidney injury, major vascular complications. LOTUS Valve = 20.3% vs. Evolut R / CoreValve Platform = 17.2%. Non-inferiority \( P = 0.003 \).

*CAUTION: The LOTUS Edge™ Aortic Valve System is an investigational device. Limited by U.S. law to investigational use only. Not available for sale. The ACURATE neo™ Aortic Valve System is CE marked. In the U.S., it is not available for use or sale. © 2017 Boston Scientific Corporation or its affiliates. All rights reserved. SH-489419-AA NOV2017
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New recommendations for switching P2Y12 inhibitors released

With the availability of different agents, both oral and intravenous, switching P2Y12 inhibitors in patients treated with dual antiplatelet therapy to prevent antithrombotic events after percutaneous coronary intervention (PCI) or acute coronary syndrome (ACS) has emerged as a frequently encountered problem in clinical practice. “For a multitude of reasons in real-world clinical practice, patients may need to switch between these different agents,” said Dominick J. Angiolillo, MD, PhD, FACC, FESC, FSCAI. “Therefore the question becomes, ‘Which is the best way to switch in order to minimize any safety concerns?’”

Since the guidelines provide limited information on this topic, a team of experts from North America and Europe published an “International Expert Consensus on Switching Platelet P2Y12 Receptor-Inhibiting Therapies” to provide physicians with a framework on when and how to switch if needed. Dr. Angiolillo will present the consensus during the “ACS & AMI Management” session at CRT 2018 on Sunday, March 4. The recommendations were originally presented at TCT 2017 in November.

Dr. Angiolillo, professor of medicine at the Florida College of Medicine – Jacksonville, said one of the main reasons for switching therapies is the increased cost with newer agents like clopidogrel, prasugrel and ticagrelor. Switching to a generic clopidogrel, which is less expensive, is very common in clinical practice. Another cause for switching is that new agents cause more bleeding. The question becomes how to switch based on the agent the patient was previously on and when he or she had PCI.

The consensus suggests giving the inhibitor under the form of a loading dose if the acute phase of treatment is being escalated—going from a less potent to a more potent agent. In the more chronic phase, the consensus says it’s OK to de-escalate with a maintenance dose, with the exception of transitioning from ticagrelor to a thienopyridine (prasugrel or clopidogrel).

If the reason for de-escalating is a bleed or concerns for a bleed, the experts also recommend switching with a maintenance dose. This is in regard to the oral therapies, as the recent introduction of an intravenous P2Y12 inhibitor canagrelor further adds to the multitude of modalities and settings in which switching therapies may occur.

“There’s a documented drug interaction based on the type of switching that is done, so providing insights on the best modalities to switch becomes very important to optimize the effect of the drug,” he said. When it comes to intravenous therapies, in general, switching from cangrelor to a thienopyridine, always give the loading dose at the end of the infusion, Dr. Angiolillo said. If you’re considering ticagrelor for your patient, you can give the drug at any time. “We also came up with recommendations since when we switch therapies, there are a number of ways of switching,” Dr. Angiolillo said. Based on the type of switch and timing of switching, our document now is able to label them so that when the topic of switching does come up, we’re able to better define what we’re speaking about.”

Endovascular track will focus on venous vascular disease, EVAR and ischemic stroke

The Endovascular Sessions for CRT 2018 will introduce several new advances as well as conventional improvements in arterial and venous vascular disease, said Mark Wholey, MD, FAHA, FSIR. Increased attention is being directed to venous disease as integrating IV ultrasound with newly designed venous stents for iliofemoral disease becomes more common.

Discussions regarding deep venous thrombosis, vena cava filters, massive pulmonary emboli and venous ulcer are being demonstrated in the management of venous disease’s expansion, he said. The Endovascular Sessions on Monday, March 5, also will include the expanding number of drug-coated balloons, in addition to comparative outcomes from the current trials and discussions on managing infratrabecular occlusive disease. Other presentations will include early data from shockwave lithotripsy, managing focal dissection with Intact Vascular’s new infratrabecular microstents and best methods for managing circumferential calcification. The endovascular aneurysm repair portion will demonstrate the overwhelming growth of endovascular aneurysm repair (EVAR). With the markedly reduced dimensions, the procedure is now done entirely percutaneously, Dr. Wholey said.

“Discussions on the expanded application of the fenestrated grafts in those patients with a very short neck will allow the fenestrated grafts to protect the renal and visceral circulation and avoid endoleaks,” he said. “This should be an excellent session as more cardiologists are involved in aneurysm repair.”

Finally, what might be the most impressive session, he added, will be solutions toward better management of ischemic stroke. There are approximately 800,000 strokes per year with only 25 percent being effectively treated. In addition, there are only around 90 advanced comprehensive stroke care centers and approximately 900 neurointerventionists in the U.S. “Obviously, we are in need of more physicians becoming involved in stroke intervention,” Dr. Wholey said. “Since the introduction of the newly designed thrombectomy devices and improved aspiration components, there has been dramatic improvement in the overall treatment of those selected patients.”

Speed is critical in the management of ischemic stroke, and it is everyone’s desire to duplicate the timing of stroke intervention with that of ST-elevation myocardial infarction.

“Cardiologists and vascular radiologists need to be trained to fill this mismatched gap,” he said. “The session will include how a cardiology program will be established, a description of the new devices and their application, choice of patients for intervention, advanced imaging to detect sites, collaterals, penumbras, managing complications and how we will expand selected community hospitals to act as intermediate stroke centers.”

International Consensus on Switching Between Oral P2Y12 Inhibitors

ACUTE/EARLY PHASE

• Give the inhibitor under the form of a loading dose if the treatment is being escalated; timing of administration irrespective of last P2Y12 inhibitor dose administered.

• If de-escalating, switch should be 24 hours after the last dose of a given drug with the use of a loading dose (with some exceptions).

LATE/VERY LATE PHASE

• De-escalate with a maintenance dose, with the exception of transitioning from ticagrelor to a thienopyridine (prasugrel or clopidogrel) where a loading dose should be used.

• Switch should be 24 hours after the last dose of a given drug (with some exceptions).
Robust mitral track reflects developments in past year

The daylong CRT 2018 Mitral Valve session will address basic concepts about mitral regurgitation (MR), imaging and indications for repair with several sessions focusing on device methods for repair and replacement.

Although on the surface the topics are similar to last year’s, the agenda offers more fleshed-out and in-depth information. This reflects the continued developments and discoveries in the mitral valve space, said Ted Feldman, MD, MSCAI, director of the catheterization laboratories at Evanston Hospital in Illinois.

“Our understanding of the problems that lead to MR has improved and gained depth over the last year,” he said. “It took us several years to distinguish between functional and degenerative MR. Now within each of those groups, we’re appreciating the importance of further subdivisions.”

Big advancements also have been made in imaging for MR assessment and planning procedures to treat MR, which will be discussed in the sessions “Imaging the Mitral Valve With CT” and “Impact of Cardiac Imaging in Mitral Clip for Patients with Functional Mitral Regurgitation.”

Thanks to the development of the U.S. FDA Early Feasibility Study Program, new trials and clinical research efforts have produced data on repair and replacement options for MR and transcatheter mitral valve replacement (TMVR). Updates on several mitral replacement trials will be presented, including NeoVasc’s TIARA-II trial, which is testing the Tiara Transcatheter Heart Valve with the Tiara Transapical Delivery System, Abbott’s Expanded Clinical Study of the Tendyne Mitral Valve System, and Medtronic’s Intrepid TMVR System in the APOLLO Trial.

The longstanding debate of whether repair or replacement is the best strategy will be discussed in “Percutaneous Mitral Valve Repair Versus Replacement: What Will Be the Dominant Procedure?”

Although transcatheter aortic valve replacement (TAVR) is now a mature procedure—about 35,000 patients were treated in 2016—TMVR lags significantly. In the same year, only a couple thousand patients were treated with percutaneous mitral devices, and the vast majority of them were with Abbott’s MitraClip™, Dr. Feldman said.

“You can see that we have a very long way to go to develop these mitral therapies,” he added. “That development process has been painfully slow until this last year, and now seems to be developing at a much more rapid pace. Mitral regurgitation is both debilitating and life-limiting. We need to recognize that the population of patients with clinically important mitral regurgitation is probably larger than the aortic valve population. The mitral therapies that we do have any good clinical evidence base for almost uniformly make patients feel better.”

TMVR specifically will be addressed in the mitral valve-in-valve and paravalvular leak session.

“This is something we’re learning more and more about with every passing year,” Dr. Feldman said. “The therapy for valve-in-valve, particularly in the mitral position, has really advanced as the FDA approval for this indication for TAVR devices has emerged over the last several months. We have had progressive improvements in our technique approaches for using interventional devices to treat paravalvular leak. I think there will be a lot of shared experience for paravalvular leak closure and a lot of discussion about best practices and procedure for valve-in-valve.”

In addition to addressing these conditions, the track also will explore more common issues of the mitral valve, like mitral annular calcification (MAC).

The implementation of balloon-expandable transcatheter devices into MAC can treat stenosis or regurgitation and remains the most challenging among mitral interventions, since MAC usually precludes any other treatment options, Dr. Feldman added. This will be addressed in the session “Implantation of Balloon-Expandable Transcatheter Heart Valves in Native Mitral Valves with Severe Mitral Annular Calcification.”

**TAVR session will discuss alternative access and the role of the surgeon**

MICHAEL REARDON, MD, WILL DISCUSS alternative access for transcatheter aortic valve replacement (TAVR) and the surgeon’s role in TAVR during the CRT Valve – Aortic session on the morning of Monday, March 5.

“My personal feeling is the sites that are going to be most successful are going to have fully involved surgeons that are involved all the way through the procedure, including the patient selection,” said Dr. Reardon, the Allison Family Distinguished Chair of Cardiovascular Research in the Department of Cardiovascular Surgery at Houston Methodist. “I feel fairly strongly about that.”

Catheter-based procedures have traditionally been the “bailiwick” of interventional cardiologists instead of heart surgeons, but Dr. Reardon argues that cardiac surgeons are well-equipped to perform the job.

“There’s a new growing group of cardiac surgeons that are following suit and becoming masters both of the world of wires and the world of open surgery,” he said. “A surgeon that can master both these areas, I think, is an extremely valuable asset to the interventional cardiologist on the TAVR team.”

Because TAVR is a national coverage decision, it requires heart surgeons to be a part of the team and involved in the active participation of TAVR. If the national coverage decision went away, then the question becomes, “How many hospitals would still have their surgeons as part of the team?”

“I think the good hospitals will still,” said Dr. Reardon, who helped assemble the first TAVR trial. “I think the surgeon brings a different perspective and will add to the interventional cardiologists’ ability to make the appropriate decisions for the appropriate patients.”

Later in the day, Dr. Reardon will make a case for using transfemoral access as an alternative access for TAVR as opposed to direct aortic access, which puts a hole in the chest.

“Alternate access that actually violates the chest wall will become diminishingly small over time,” he said. “Transfemoral is likely to stay the most commonly used one.”

In other sessions at CRT, Dr. Reardon will discuss his upcoming bicuspid valve trial with Medtronic. He also will discuss TAVR in low-risk populations and argue that the interventional cardiology world is ready for objective performance criteria trials, since they are less expensive and easier to run.

“I don’t think there will be another trial randomized against surgery,” Dr. Reardon said. “This is it. There may be trials randomizing valve against valve, but even those are no longer necessary. It’s time for these valves to be done on an objective performance criteria.”
n the 1970s, Andreas Grützig, working in Switzerland, sought to miniaturize the Dotter technique so he could dilate arteries in the heart. Through experimental testing, Dr. Grützig’s idea eventually turned into balloon angioplasty, or what is known as percutaneous coronary intervention (PCI). He performed the first human coronary balloon angioplasty at University Hospital, Zurich in 1977. Now four decades later, his breakthrough procedure—a less-invasive method of revascularization compared to surgery—has evolved from balloons only to flexible stents, drug-eluting stents and research into bioabsorbable scaffolds.

Following Dr. Grützig’s successful first intervention, he began teaching courses on the procedure. In January 1980, Spencer King, MD, suggested he visit Emory University, where he was practicing. Dr. Grützig agreed and joined the team at Emory. The duo began offering the same courses at Emory, but this time, to a much larger crowd—400 to 500 people. Many other people started joining the movement and teaching courses.

“Angioplasty has revolutionized cardiology and the necessity to train people to learn from each other has expanded dramatically,” Dr. King said. “Courses from the ACC, TCT, the European courses, CRT and others have driven education in the field.”

Over the years, the technique improved and wires enabled marked expansion to more difficult cases. The late Geoffrey Hartzler, MD, pioneered PCI in acute myocardial infarction patients.

“Angioplasty became an incredible tool to treat myocardial infarctions,” Dr. King said. “Now with this, a heart attack could be stopped in its track. Before, you had to open the chest and do a bypass surgery, but it was cumbersome and fraught with complications.”

In 1987, Dr. King, with the help of other investigators including William Weintraub, MD, conducted the National Heart, Lung, and Blood Institute-sponsored Emory Angioplasty versus Surgery Trial (EAST). The researchers performed a prospective, randomized comparison of angioplasty with surgery in patients with multivessel disease, finding there was no significant difference. But the procedure kept evolving.

“Stents were the major breakthrough of the late 1980s and began to be the dominant therapy,” Dr. King said. “However, we found out they also were associated with restenosis. About this time in the early 1990s, I got a call from Dr. Gotesman of Hadassah University in Jerusalem asking if I would take a fellow from their program, whose name was Ron Waksman. During his time with us, we began working on how to address restenosis with radiation therapy. That’s when brachytherapy was developed as a method to block the restenosis.”

The method blocks restenosis by interfering with the cell cycle. Also during this time, others began developing drug-coated stents to control restenosis.

They became the dominant stents from that point on until today. “In the last decade, bioresorbable scaffolds have been tried with great enthusiasm, but later with trepidation as thrombosis became more of a concern,” Dr. King said.

Bioresorbable scaffolds are of broad interest because, after they are deployed and release drugs for the prevention of restenosis, they slowly dissolve, leaving behind a cleared artery, but not the metal cage of a stent. The U.S. FDA did approve the Abbott vascular scaffold (BVS) in July 2016, but the company halted sales in September 2017.

Many other technologies—such as absorbable metals and polymers—are emerging, but “we’re still waiting for the next breakthrough,” Dr. King said. That’s why meetings, especially CRT, are so important.

“We need to bring together not only the investigators, clinicians, and industry, but also the research enablers, agencies that support research like the NHLBI, and the agencies that regulate new device developments like the FDA,” Dr. King said. “The CRT meeting brings together all of these components to work on the further expansion of interventional cardiology.”

Network with industry experts, catch up with your colleagues, and enjoy cocktails, hors d’oeuvres and music! This highly anticipated social event will take place on Sunday, March 4 from 5:30 – 7:00 PM in the Exhibit Hall.
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Course Description
This hands-on workshop is intended for the practicing interventional cardiologist who plans to perform procedures involving left atrial access, including LAA closure, transcatheter mitral valve repair and/or mitral valvuloplasty. Expert faculty will provide didactic learning, followed by hands-on rotators using simulators, wet models, and devices.

Agenda
- Interventional Patho-Biology: Transseptal Crossing and Left Atrial Interventions
- Step by Step Technique and Imaging Interpretation (TEE)
- Basic Technique 101
- Interventional Tool Kit and Complication Management
- Hands on Training

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Theater 2 - Exhibit Hall
Sunday, March 4, 2018
9:30 am –11:00 am

Monday, March 5, 2018
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Cardiovascular Research Technologies 2018