

# CARDIOLOGY



DECEMBER 2025

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**American College of Cardiology**

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CORONARY ANALYSIS



## The Digital Operating Room: Patient-Specific Modeling For Optimal Structural Heart Outcomes

STRETCH ANALYSIS

2ND VALVE ANALYSIS

THV APPPOSITION



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The ACC was live from AHA 2025 in New Orleans as this issue went to print. Check out all the live coverage of late-breaking science, key trends and JACC simultaneous publications at [ACC.org/AHA2025](https://acc.org/AHA2025).



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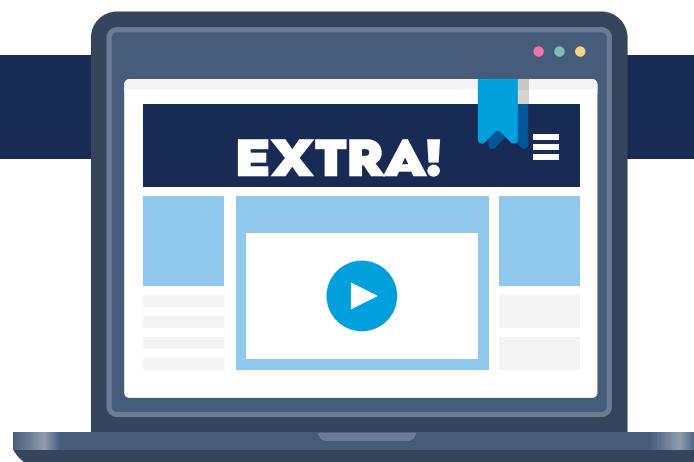
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To learn more about the Collaborative Maintenance Pathway for general cardiology, heart failure and interventional cardiology, visit [ACC.org/CMP](https://acc.org/CMP).

## Bonus Content! Online-Extra Articles!

Explore more with online-only content at [ACC.org/Cardiology](https://acc.org/Cardiology).

Read a perspective from a senior internal medicine resident and future quality improvement chief about how **ACC 2025 Quality Summit** underscores the importance of collaboration, mentorship and a culture of continuous improvement in shaping cardiovascular care. In another perspective, a fellow who attended **ACC Legislative Conference** emphasizes that advocacy is a shared responsibility and that progress in cardiovascular health requires a united effort from every member of the care team. Plus don't miss reading about the work of **Fernando Wyss Quintana, MD, PhD, FACC**, recipient of the 2025 International Service Award, to build sustainable health systems in Guatemala.



## WHAT'S INSIDE

- 02 EDITORS' CORNER
- 03 PULSE OF ACC
- 06 JACC IN A FLASH
- 08 JOURNAL WRAP
- 10 **NEW IN CLINICAL GUIDANCE**  
Evaluation, Management of ATTR-CM; JACC Focus Issue on HBP Guideline
- 11 NUMBER CHECK
- 12 **FEATURE**  
Expanding the Cardiologist's Lens: The Urgency of PAD Management
- 14 **PRIORITIZING HEALTH**  
hsCRP: A Promising Risk Assessment Tool
- 16 **COVER STORY**  
The Digital Operating Room: Patient-Specific Modeling For Optimal Structural Heart Outcomes
- 20 **FEATURE**  
"Fear the FOMO: Why You Can't Miss ACC.26"
- 22 **FEATURE**  
Lipoprotein(a): An Independent Risk Factor For CV Disease
- 23 **FEATURE**  
Cardio-Obstetrics Essentials: Advancing Care For Women's Heart Health
- 24 **FOCUS ON INTERVENTION**  
TCT 2025: Transformative Trials Redefining CV Intervention
- 26 **FEATURE**  
Maximizing Recovery: Cardiac Rehab in Contemporary CV Care
- 28 **QUALITY IMPROVEMENT FOR INSTITUTIONS**  
Baylor St. Luke's Medical Center: A Legacy of Continuous Improvement
- 30 **HEART OF HEALTH POLICY**
- 32 **ACC MISSION IN ACTION**

## Cardiology Magazine: Evolving With You in 2026

For more than five decades, *Cardiology* magazine has been the ACC's flagship member publication, serving as a trusted source of knowledge, perspective and connection for cardiovascular professionals worldwide. What began in the 1970s as a simple, one-color member newsletter has grown into a dynamic, much-read publication that reflects the ever-changing landscape of cardiovascular medicine and the needs of ACC members.

Over the years, *Cardiology* has chronicled the evolution of cardiovascular care, spotlighted emerging trends, and provided a forum for commentary and thought leadership. It has introduced readers to current and future leaders in the field, shared inspiring stories and delivered insights that help shape practice and policy. Through all these changes, one thing has remained constant: our commitment to delivering high-quality journalism and member value.

As we look toward the New Year, we're excited to announce that *Cardiology* is evolving once again - this time with you, our readers, at the center of the transformation. We've listened carefully to your feedback and studied publishing trends to ensure that the magazine continues to meet your needs in a fast-paced, digital-first world. The result? A refreshed *Cardiology* magazine designed to be more portable, more streamlined and more impactful.

Starting in 2026, you'll notice a few key changes:

- **A Smaller, More Portable Print Format:** We're introducing a size that's easier to carry and read on the go, without sacrificing the depth and quality you expect.
- **Streamlined Frequency:** To align with your preferences and optimize content delivery, *Cardiology* will publish **10 issues per year** instead of monthly. This change allows us to focus on delivering richer, more curated content in every issue. Look for combined issues in January/February and July/August.

While the look and feel may be new, some things will never change. You can continue to count on:

- **Trusted, High-Quality Journalism:** Our editorial standards remain as rigorous as ever.
- **Insightful, Inspiring Stories:** From clinical breakthroughs to personal journeys, we'll keep bringing you the stories that matter.
- **A Steadfast Commitment to Excellence and Member Value:** Every page is crafted with your professional growth and engagement in mind.
- **A Continued Digital Presence:** Find us online at [ACC.org/Cardiology](https://www.acc.org/Cardiology) and look for our regular eTOC email highlighting the latest content and online-only features.

These updates reflect our ongoing mission: to evolve with you and deliver the knowledge, perspective and connection that define the ACC community. We believe these changes will make *Cardiology* even more relevant and enjoyable, and we hope you agree.

Thank you for being part of this journey. Here's to a new chapter for *Cardiology* magazine in 2026 - redesigned, refreshed and ready to serve you better. Happy holidays to all who celebrate. ■



Peter C. Block  
MD, FACC



John Gordon Harold  
MD, MACC

#### Editors-in-Chief

Peter C. Block, MD, FACC  
John Gordon Harold, MD, MACC

#### ACC Chief Medical Officer

Richard J. Kovacs, MD, MACC

#### ACC Clinical Content Editor-in-Chief

Fred Kusumoto, MD, FACC

#### Publisher

American College of Cardiology

#### ACC CEO

Cathleen C. Gates

#### ACC Chief Communications Officer

Shalen Fairbanks

#### Managing Editor

Mary Mosley

#### Contributing Writers

ACC Communications Team  
Debra Gordon, MSc

#### Design, Web and Production

ACC Creative and Branding Team

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#### Advertising

M. J. Mrvica Associates, Inc.  
Mark Mrvica  
[markmrvica@mrvica.com](mailto:markmrvica@mrvica.com)

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E-mail [cardiologyeditor@acc.org](mailto:cardiologyeditor@acc.org)

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The American College of Cardiology (ACC) is a global leader dedicated to transforming cardiovascular care and improving heart health for all. For more than 75 years, the ACC has empowered a community of over 60,000 cardiovascular professionals across more than 140 countries with cutting-edge education and advocacy, rigorous professional credentials, and trusted clinical guidance. From its world-class JACC Journals and NCDR registries to its Accreditation Services, global network of Chapters and Sections, and CardioSmart patient initiatives, the College is committed to creating a world where science, knowledge and innovation optimize patient care and outcomes. Learn more at [www.acc.org](https://www.acc.org) or connect on social media at @ACCinTouch.

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## ACC ANNOUNCES NEW FUSTER PREVENTION FORUM

The ACC is proud to introduce the Fuster Prevention Forum, an exclusive educational experience honoring the legacy of **Valentin Fuster, MD, PhD, MAAC**. This innovative program will equip clinicians with practical tools and frameworks to educate children, parents and educators on nutrition, physical activity and emotional well-being.

Chaired by **Pamela Bowe Morris, MD, FACC**, and **Edward T. A. Fry, MD, MAAC**, the Forum aims to foster skills and confidence to develop sustainable, community-based prevention initiatives and build a collaborative network of clinicians committed to advancing a culture of prevention in schools and communities.

The inaugural cohort will convene for a two-day training at ACC's Heart House in Washington, DC, June 12 to 13, 2026, followed by a webinar three to six months later to review progress and share best practices. Participants who complete the course will be recognized as Experts in Primordial Prevention and return to their communities equipped with curriculum materials, digital content and practical toolkits to implement change. ■



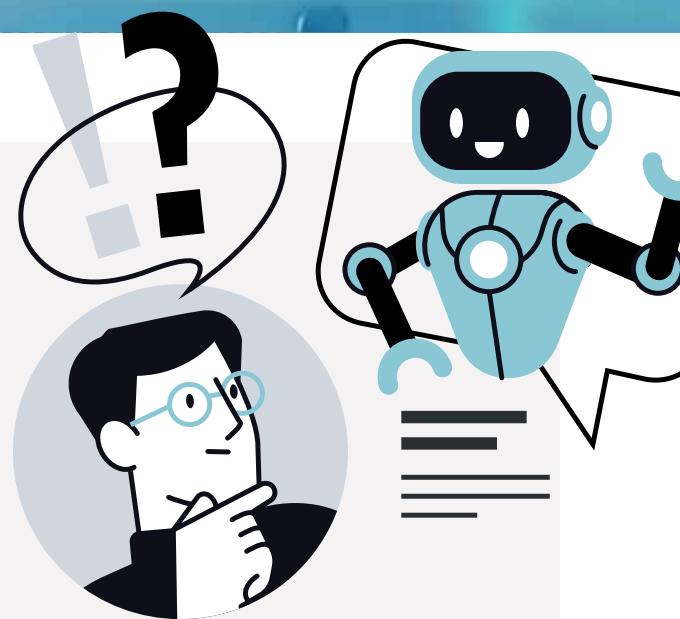
## ACC Partners With OpenEvidence to Advance AI in Cardiovascular Care

The ACC and OpenEvidence have formed a strategic partnership to accelerate the integration of cardiovascular clinical guidance into point-of-care decision-making. By combining ACC's leadership in cardiovascular science with OpenEvidence's generative AI technology, clinicians will gain rapid access to trusted, evidence-based content to support shared decision-making.

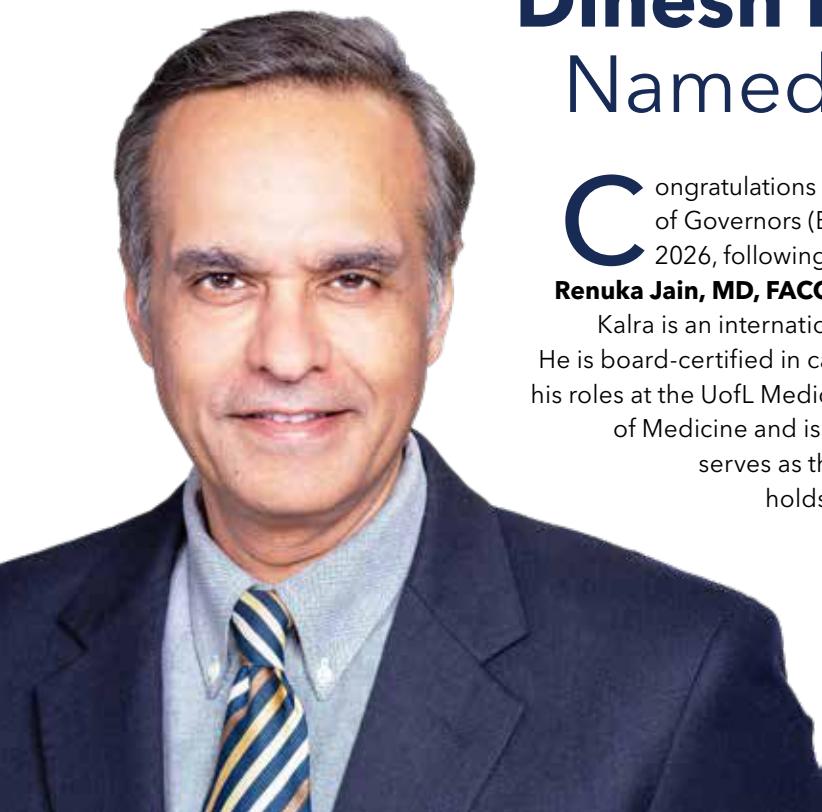
"At the American College of Cardiology, our mission is to transform cardiovascular care and improve heart care for all because patients deserve care that's not only informed by the latest scientific evidence, but also delivered with confidence and compassion," said ACC CEO **Cathleen C. Gates**. "Our collaboration with OpenEvidence will allow us to responsibly integrate AI into clinical workflows, ensuring that patients benefit from timely, evidence-based care without compromising safety, transparency or the trusted judgment of their clinicians." ■

OpenEvidence CEO **Daniel Nadler, PhD**, added: "Clinicians across every specialty rely on the work of the ACC to guide evidence-based care. We're thrilled to partner with the organization that defines the foundation for cardiovascular practice, bringing their trusted expertise to the point of care through responsible, generative AI." ■

The partnership will include an expert work group to identify high-impact areas and knowledge gaps, development of supplemental materials, as well as the launch of an ACC/OpenEvidence AI Resource Center and podcast series. Attendees at ACC's Annual Scientific Session can explore these innovations at the ACC Future Hub. ■



## Dinesh Kalra, MD, FACC, Named Next BOG Chair-Elect



**C**ongratulations to **Dinesh Kalra, MD, FACC**, for being named the next chair-elect of the ACC Board of Governors (BOG). Kalra, who is currently ACC governor for Kentucky, will assume his role in April 2026, following ACC.26 in New Orleans, and will assume the role of BOG Chair from 2027 to 2028 after **Renuka Jain, MD, FACC**.

Kalra is an international expert in multimodality cardiac imaging, as well as preventive cardiology and lipidology. He is board-certified in cardiology, echocardiography, CT, CMR, lipidology and nuclear cardiology. In addition to his roles at the UofL Medical Center and School of Medicine, Kalra serves as vice chair for quality in the Department of Medicine and is on the Board of Directors, is chair of the Quality Assurance Committee for Cardiology, and serves as the director of the Heart Board for the Cardiovascular Service Line at UofL Hospital. He also holds an endowed chair position in the Jewish Hospital Cardiovascular Innovation Institute.

"The ACC has been my professional home since my training over 20 years ago, guiding my growth in clinical practice, advocacy, leadership and personal development," says Kalra.

"Serving as chair of the BOG is both a tremendous honor and a profound responsibility. I see it as an opportunity to give back to an organization that exemplifies what we strive for as clinicians - to lead with purpose, vision, collaboration and compassion, advancing cardiovascular health for all." ■

## Innovation, Strategy and Leadership Take Center Stage at Fall CV Transforum

**T**he MedAxiom Fall CV Transforum brought together cardiovascular leaders from across the country to tackle some of the most pressing challenges and opportunities shaping the specialty today.

Kicking off with an in-depth look at the current state of cardiovascular care, general sessions explored how programs can adapt to growing patient volumes, workforce shortages and rapidly advancing technologies. Keynote sessions emphasized actionable insights on transforming care delivery, from rethinking the cardiovascular workforce model to embracing value-based care strategies that drive both clinical and operational excellence.

Throughout the meeting, expert panels, breakout groups and leadership discussions highlighted the importance of data-driven strategy and innovation in driving sustainable growth. Attendees heard real-world examples of health systems leveraging analytics to improve patient outcomes and streamline performance, while thought leaders examined the evolving role of artificial intelligence, digital health and new care models in advancing cardiovascular practice. The focus on collaboration and continuous improvement reinforced MedAxiom's mission to empower organizations to thrive amid ongoing change.

As cardiovascular care continues to evolve, sessions underscored that transformation is not optional - it's essential. The latest chapter in the **ACC and MedAxiom Care Transformation Initiative**, "*Broadening the Team-Based Care Model: A Transformational Approach to Cardiovascular Care Delivery*," offers a timely next step for teams seeking to put these lessons into practice. The workbook provides a practical framework for building collaborative, high-performing care teams grounded in clear roles, communication and performance excellence. **Scan the QR code** to download the paper.



Scan this QR code to access previous chapters on AI and ambulatory surgery centers, respectively. ■





## Rising Impact: JACC: CardioOncology's Influence Grows

**J**ACC: CardioOncology has marked a significant milestone, with its latest reported Impact Factor rising to 13.4 and ranked in the top 10. This updated impact factor underscores the journal's rapidly growing influence in the intersecting fields of cardiology and oncology and reflects its role as a key platform for high-impact, multidisciplinary research in cardio-oncology. Read the latest issue at [JACC.org](http://JACC.org). ■



## A Royal Honor

**T**he Royal College of Physicians of Ireland (RCPI) honored **Robert M. Califf, MD, MACC**, a distinguished physician, researcher and educator who has served twice as commissioner of the U.S. Food and Drug Administration, with an honorary fellowship during a special admission ceremony this Fall. The RCPI honor is given to individuals from around the world who have made a significant contribution to medicine and their respective specialty. *Cardiology* Editor-in-Chief **John Gordon Harold, MD, MACC**, also an honorary fellow who nominated Califf, joined him in Dublin to deliver the citation. ■



## Sustaining Community Health in Chicago

**B**uilding on the momentum of the ACC's Chicago Community Health Fair earlier this year, the Illinois Chapter has launched a monthly program at the Salvation Army Ray & Joan Kroc Corps Community Center and is looking to expand to other areas of Chicago as opportunities allow.

"Guided by the principles of health equity, this initiative is designed to strengthen community ties, improve cardiovascular health literacy and promote healthier behaviors," said **Nausheen Akhter, MD, FACC**.

The inaugural session supported by dedicated ACC Illinois Chapter Social Justice Committee volunteers included blood pressure screenings, a group exercise class led by exercise physiologist **Nana Anim Asante-Apeatu, MSc**, and a health literacy and hypertension talk delivered by **Alana Lewis, MD, FACC**. Attendees came away with CardioSmart resources and other tools and were encouraged to return with friends and family in future months.

"Through sustained, community-based initiatives, we aim to empower patients, foster trust with cardiovascular health professional and address the health disparities faced by underserved populations in Illinois," said Akhter.

By creating a consistent presence in the community, the Chapter aims to establish a sustainable model that delivers long-term impact and builds on the goals set during the Chicago Fair. Looking ahead, ACC will continue its commitment to health equity with the New Orleans Community Health Fair on March 22, held the Saturday leading up to ACC.26. Living in New Orleans? Help spread the word. More information is available at [ACC.org/HealthFair](http://ACC.org/HealthFair). ■



## TCT 2025 Science Published Across JACC Journals

Coinciding with research presented during TCT 2025, some 30 manuscripts including late-breaking trials and editorial comments were simultaneously published across the JACC Journals. Read below for highlights. **Scan the QR code** for the complete list of simultaneous publications, wrap-up videos, abstract supplement and more.



### SUMMIT-MAC: TMVR With Tendyne in MR, Severe MAC

Transcatheter mitral valve replacement (TMVR) with use of the Tendyne transcatheter mitral valve system was successful in treating mitral valve disease due to mitral annulus calcification (MAC), and significantly improved heart failure (HF) symptoms and quality of life (QOL), according to a first report of the primary outcomes of the SUMMIT-MAC trial presented at TCT 2025 and simultaneously published in JACC.

In what they believe is the first prospective clinical trial to evaluate the use of the Tendyne system for severe MAC, **Paul Sorajja, MD, FACC**, et al., analyzed 103 nonrandomized patients with severe MAC and mitral regurgitation (MR) or stenosis, who underwent treatment with Tendyne. All patients were at high surgical risk, and an echocardiography core laboratory performed assessments of mitral disease.

The primary endpoint was freedom from HF hospitalization and all-cause mortality at 12 months post-index procedure, and adverse events were adjudicated by an independent clinical events committee.

Of included patients (55% women, mean age of 78 years) in this multicenter, multicohort investigation, MR was present in nearly all

at baseline (97%). Additionally, technical success was achieved in 94% of patients, with a 30-day mortality of 7%.

Of note, the primary endpoint was met: 60% at six months, beating the performance goal of 43%. Moreover, QOL improved significantly ( $18 \pm 24$  points;  $p < 0.0001$ ) as did HF symptoms (NYHA Class I/II, 30% vs. 88%, paired baseline vs. 12 months;  $p < 0.0001$ ).

Sorajja and colleagues note the need for “safe and effective [TMVR] options” for this patient population. “The availability of this transcatheter option addresses a significant treatment gap for patients with severe MAC, who face high surgical risk and lack of effective medical therapy,” they write.



Sorajja P, Thourani VH, Rogers JH, et al. *JACC* 2025; Oct. 27: <https://doi.org/10.1016/j.jacc.2025.10.025>.

### STRIVE: Does Alteplase Improve Microvascular Obstruction, MACE in Primary PCI?

Targeted adjunctive intracoronary delivery of the low-dose recombinant tissue plasminogen activator alteplase does not improve microvascular obstruction or major adverse cardiovascular events (MACE) in patients undergoing primary PCI for a large territory STEMI and high thrombus burden, according to results from the STRIVE trial presented at TCT 2025 and simultaneously published in JACC.

In this multicenter trial, **Shamir R. Mehta, MD, MSc, FACC**, randomized 210 patients to receive alteplase 10 mg, alteplase 20 mg or placebo, which, after antegrade reperfusion was established, was administered directly into the infarct-related artery using a delivery catheter.

The primary outcome was the composite of MACE, distal embolization or failure to achieve  $\geq 50\%$  ST-segment resolution at 30 minutes post PCI, or myocardial blush grade 0/1. The authors defined MACE as the composite of cardiovascular death, myocardial reinfarction, cardiogenic shock or new onset heart failure at 30 days.

Of included patients, 207 (25% women, mean age of 63 years) patients received study drug: 68 patients received alteplase 10 mg, 69 received alteplase 20 mg and 70 received placebo. The median time from symptom onset to randomization was 2.9 hours.

In the two alteplase groups, the primary outcome occurred in 73 patients vs. 37 patients in the placebo group (relative risk 1.00;  $p > 0.99$ ). Results were consistent for each dose group vs. placebo, and

for all components of the primary outcome. Additionally, during study drug administration, there was a trend to more episodes of ventricular fibrillation in the alteplase groups vs. the placebo group (10% vs. 1%; relative risk 6.86;  $p = 0.06$ ). Of note, across all groups, major or clinically significant bleeding occurred in one patient who received alteplase 20 mg.

Mehta and colleagues emphasize that “improving microvascular obstruction and subsequent clinical outcomes remains a major

challenge for STEMI patients undergoing primary PCI with large thrombus burden.” Including these results, “no adjunctive therapy to date has improved outcomes once epicardial flow has been restored.” Finally, they write, these data not support the routine administration of this therapy in patients with STEMI. ■



Mehta SR, Pinilla-Echeverri N, Tiong D, et al. *JACC* 2025; Oct. 27: <https://doi.org/10.1016/j.jacc.2025.10.008/>.

# REC-CAGEFREE I: DCB vs. DES in de Novo CAD

Compared with drug-eluting stent (DES) implantation, use of drug-coated balloons (DCB) as an alternative for treating de novo coronary artery disease (CAD) was associated with a significantly higher rate of cardiovascular death, target vessel myocardial infarction (TV-MI) and clinically and physiologically indicated target lesion revascularization (TLR) at three years, based on new findings from REC-CAGEFREE 1, presented at TCT 2025 and simultaneously published in *JACC*.

Conducted across 43 sites in China, researchers randomly assigned 2,272 patients with de novo CAD to either DCB with the option of rescue stenting (n=1,133) or DES (n=1,139) following successful lesion predilation. The primary outcome was the device-oriented composite endpoint (DoCE), which included cardiovascular death, TV-MI, and clinically and physiologically indicated TLR.

The newest analysis looks at three-year outcomes, which show the DoCE occurring in 8.2% of patients in the DCB group compared with 5.0% in the DES group (difference, 3.21%; 95% CI, 1.17-5.26; p=0.002). Importantly, the higher DoCE rate in the DCB group was primarily due to

the increased incidence of clinically and physiologically indicated TLR. Cardiovascular mortality and TV-MI rates were similar between groups.

In other findings, 9.4% of patients in the DCB group received rescue DES. Of those patients, 10.4% had DoCE at three years. For patients in the DCB group without rescue stenting, 7.9% had DoCE.

“Based on current data, we considered that DES should remain the preferred treatment option for patients with de novo [CAD], especially in the large vessels,” said **Ling Tao, MD, PhD, Xingqiang He, MD**, et al.

Over the course of three years, Tao and colleagues said DoCE occurred more frequently with DCB compared to DES in the first year, but this gap gradually decreased over the subsequent years. “This risk pattern highlights the need for long-term follow-up to understand the impact of DCBs on vessels,” they said. ■

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Tao L, He X, Shen G, et al. *JACC* 2025; Oct. 27: <https://doi.org/10.1016/j.jacc.2025.10.027>.

# PROCTOR: SVG PCI vs. Native Vessel PCI in Post-CABG Patients With Graft Failure

In patients presenting with graft failure after a CABG, PCI of the saphenous vein grafts (SVG), compared with native vessels, was associated with better one-year clinical outcomes, based on findings from the PROCTOR trial presented at TCT 2025 and simultaneously published in *JACC*. In presenting the findings, **Ruben W. de Winter, MD**, noted these results were primarily driven by lower rates of PCI-related myocardial infarction (MI) and clinically driven target coronary territory revascularization.

The trial, which was conducted across 14 centers in Europe, randomized 220 patients with significant SVG stenosis and a Heart Team-defined clinical indication for revascularization to receive either native vessel PCI (n=108) or SVG PCI (n=112). The primary endpoint was major adverse cardiac events at one year, including all-cause mortality, nonfatal target coronary territory MI or clinically driven target coronary territory revascularization. The average age of participants was 73 years and 85% were male.

At one year, the primary endpoint occurred in 34% of patients in the native vessel PCI group (n=37) compared with 19% of patients in the SVG PCI group (n=21). Broken down by event, researchers observed no significant difference in all-cause mortality between the two groups. However, patients assigned to native vessel PCI experienced both nonfatal target coronary territory MI and clinically driven target coronary territory revascularization more frequently. The incidence of PCI-related MI was 1% in the SVG PCI group vs. 13% in the native vessel PCI group.

“Patients with prior CABG represent a clinically challenging population characterized by older age, multiple comorbidities, and complex coronary anatomy complicating repeat revascularization strategies,” says de Winter and colleagues. “Observational cohort studies have reported better outcomes with native vessel PCI compared with SVG PCI, informing current guideline recommendations to favor the bypassed native coronary artery when technically feasible. ... The findings of the PROCTOR trial appear to challenge the conclusions drawn from observational data.”

In a related editorial comment, **Yousif Ahmad, MD, PhD, FACC, Rohin K. Reddy, MBBS, and Robert W. Yeh, MD, MSc, FACC**, call the PROCTOR trial “illuminating,” noting that it “advances the field by demonstrating native vessel PCI should not be considered the default approach, particularly if the native intervention is likely to be exceptionally complicated and higher risk, even if feasible.” Additionally, they applaud the study for more broadly revealing “the competition between evidence and dogma in the interventional community.” They write: “We must stop relying on expert consensus and flawed observational data to guide our practice.” ■

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De Winter RW, Hoek R, Walsh R, et al. *JACC* 2025; Oct. 28: <https://doi.org/10.1016/j.jacc.2025.09.1577>.



## PARTNER 3: TAVR vs. Surgery in Low-Risk Patients at 7 Years

**A**mong low-risk patients with severe, symptomatic aortic stenosis who underwent either TAVR or surgery, the incidence of death, stroke or rehospitalization at seven years was similar across both groups, based on the newest findings from the PARTNER 3 trial. The results, presented at TCT 2025 and simultaneously published in *NEJM*, also appeared to show similar rates of valve durability and patient-reported outcomes.

A total of 1,000 patients were enrolled in the trial and were randomly assigned to undergo transfemoral TAVR or surgery. The first primary endpoint was a nonhierarchical composite of death, stroke or rehospitalization related to the procedure, the valve or heart failure, while the second primary endpoint involved a hierarchical composite of death, stroke and the number of rehospitalization days related to the procedure, the valve or heart failure. Clinical, echocardiographic, valve-durability and health-status end points were also assessed. The current findings assess long-term outcomes through seven years.

In the analysis of the first primary endpoint, the Kaplan-Meier estimate of the incidence of an endpoint event was 34.6% with TAVR and 37.2% with surgery, according to **Martin B. Leon, MD, FACC, Michael J. Mack, MD, MACC**, et al. The win ratio for the second primary endpoint was 1.04.

Broken down by event, the Kaplan-Meier estimates for the incidence of death was 19.5% and 16.8% in the TAVR and surgery groups, respectively, while stroke was 8.5% and 8.1% and rehospitalization was 20.6% and 23.5%. The percentage of bioprosthetic valves that failed was 6.9% in the TAVR group and 7.3% in the surgery group.

“A consistent finding in PARTNER 3 follow-up analyses has been an attenuation of the between-group difference in primary endpoint events, which favors TAVR over surgery in the first year with no between-group differences apparent during longer follow-up,” write the authors. ■

Leon MB, Mack MJ, Pibarot P et al. *NEJM* 2025; Oct. 25: DOI: 10.1056/NEJMoa2509766.

## PROMISE and iMODERN Trials Offer Fresh Insights Into MINOCA and STEMI Management

**L**ate-breaking science presented at TCT 2025 addressed immediate PCI guided by instantaneous wave-free ratio (iFR) vs. deferred PCI of nonculprit lesions in acute STEMI patients, as well as management of patients with myocardial infarction with nonobstructive coronary arteries (MINOCA).

In the **iMODERN** trial, simultaneously published in *NEJM*, three-year outcomes showed immediate PCI guided by iFR was not superior to deferred PCI guided by cardiac stress MRI of nonculprit coronary artery lesions in patients with acute STEMI.

Researchers randomly assigned 1,146 patients with STEMI and at least one nonculprit lesion who had undergone successful primary PCI to receive immediate iFR-guided PCI (n=558) or deferred cardiac stress MRI-guided PCI (n=588) within six weeks of randomization. The primary endpoint was a composite of death from any cause, recurrent MI or hospitalization for heart failure at three years. The mean age of participants was 63 years and 78% were men.

Overall results showed a primary endpoint event occurred in 50 patients (9.3%) in the iFR group and in 55 patients (9.8%) in the MRI group. In addition, serious adverse events occurred in 145 patients in the iFR group and in 181 in the MRI group. The secondary endpoints of cardiac death, target lesion failure, major bleeding and unstable angina at three years occurred in a similar number of patients across both treatment groups, according to **Robin Nijveldt, MD, PhD, FACC**, who presented the findings.

In the **PROMISE** trial, researchers found that a stratified treatment of patients with MINOCA, significantly improved angina status at 12 months (the primary endpoint) and was also feasible and safe, compared with standard care.

Researchers randomly assigned participants 1:1 to either stratified therapy or standard care. Stratified therapy involved an advanced

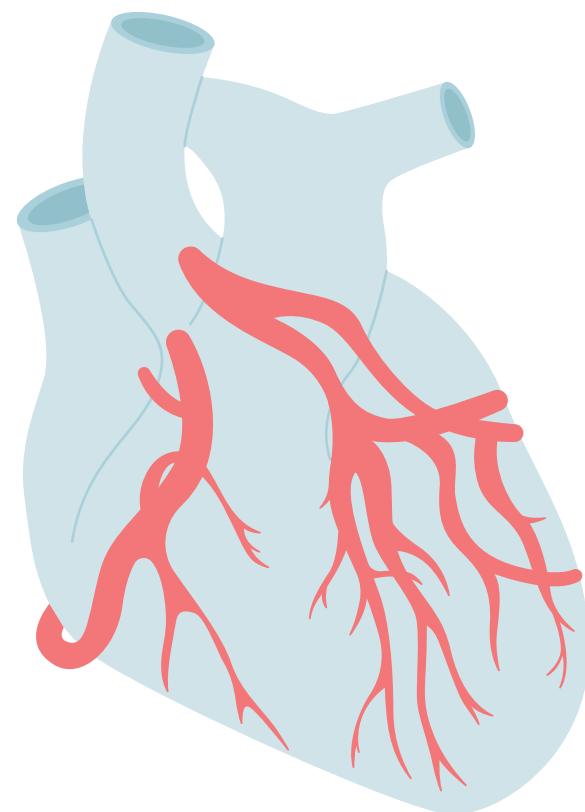
diagnostic work-up to uncover the mechanism of MINOCA, coupled with tailored therapy targeting the specific mechanism of MINOCA, while standard care included only coronary angiography and standard therapy for acute coronary syndrome.

“PROMISE is the first randomized trial evaluating the management of MINOCA patients,” said **Rocco A. Montone, MD, PhD**, in presenting the findings. In addition to improved angina benefits, Montone noted there were no adverse events related to the advanced diagnostic workup, as well as proven diagnostic utility, with reclassification of initial suspected diagnosis occurring in 75.5% of cases.

The trial did have limitations, with Montone noting early termination due to no definite conclusions of hard endpoints and its open label design. However, he closed with a Latin quote from Seneca: “If one does not know to which port one is sailing, no wind is favorable.” ■

Nijveldt R, Maeng M, Beijinck CWH, et al. *NEJM* 2025; Oct. 28: DOI: 10.1056/NEJMoa2512918.

Montone R, Cosentino N, Gorla R, et al. *Eur Heart J* 2025; Oct. 28:ehaf917, <https://doi.org/10.1093/eurheartj/ehaf917>.



# ANDES: DOACs vs. DAPT After LAAC in Patients With Nonvalvular AFib

The use of direct oral anticoagulants (DOACs) following transcatheter left atrial appendage closure (LAAC) in patients with nonvalvular atrial fibrillation (AFib) was not superior to DAPT in preventing device-related thrombosis (DRT), based on findings from the ANDES trial presented at TCT 2025 and simultaneously published in *Circulation*. However, researchers did note DOACs use was associated with an improved safety profile.

In what is the largest trial to date comparing DOACs with DAPT for transcatheter LAAC, researchers randomized 510 patients (average age of 77 years; 35% women) to DOACs or DAPT. The primary outcome was DRT as determined by TEE at 60 days after LAAC. The primary safety outcome included all-cause mortality, stroke, bleeding or DRT.

Of the 399 patients who ultimately underwent TEE and were receiving the allocated treatment at 60 days after LAAC, the primary outcome occurred in three patients (1.5%) receiving DOACs and eight patients (4.1%) receiving DAPT. The safety outcome occurred in 52 patients (22.5%) in the DOACs group compared with 82 patients (34.9%) in the DAPT group, largely due to a lower rate of bleeding events among those assigned to DOACs. Researchers cautioned that the results should be confirmed in future larger studies.

“While waiting for further evidence, these findings suggest that the short-term use of DOAC may be a reasonable and likely safer antithrombotic strategy in LAAC recipients,” said

**Josep Rodés-Cabau, MD, PhD**, in presenting the findings. ■

Rodés-Cabau J, Nombela-Franco L, Cruz-Gonzales I, et al. *Circulation* 2025; Oct. 26: <https://doi.org/10.1161/CIRCULATIONAHA.125.077469>.



## ENCIRCLE: Percutaneous Transseptal TMVR System in Patients Not Eligible For Surgery or TEER

Percutaneous transseptal mitral valve replacement (TMVR) using the SAPIEN M3 system effectively reduced mitral regurgitation (MR) with low rates of complications and mortality in patients with symptomatic, moderate-to-severe MR who were not candidates for conventional surgery or transcatheter edge-to-edge repair (TEER).

The ENCIRCLE trial, the results of which were presented at TCT 2025 and simultaneously published in *The Lancet*, ultimately involved a total of 287 patients from the U.S., Canada, Europe, Israel and Australia who had MR  $\geq 3+$ , NYHA Class  $\geq II$  and were unsuitable for surgery or TEER due to clinical, anatomic or technical considerations. The balloon-expandable, dedicated SAPIEN M3 mitral transcatheter heart valve was implanted in each patient and follow-up was conducted at 30 days, six months and one year.

In overall findings, the primary endpoint - the composite of all-cause mortality and rehospitalization for heart failure at one year compared to a prespecified performance goal of 45% - was 25.2%. All-cause death and heart failure hospitalization rates were 13.9% and 16.7%, respectively. Additionally, improvements in MR grade were observed across all patients, with more than 95% having  $\leq 1+$  total MR at 30 days and one year.

Researchers also noted the TMVR system had a procedural safety profile similar to TEER and that patients experienced clinically meaningful and durable improvements in symptoms and quality of life.

“Percutaneous transseptal TMVR had a low mortality rate while providing a significant reduction in [MR] severity and providing meaningful and durable improvements in functional status and quality of life,” said **David Daniels, MD**. “These findings will help guide clinical practice by providing an alternative treatment option for patients who are not suitable for conventional surgery or TEER procedures.”

Additionally, Daniels and colleagues say their findings could allow for “future reintervention with percutaneous transseptal mitral valve-in-valve implantation in the event of structural valve deterioration,” noting that “reintervention after failed TEER remains a major limitation.” ■

Guerrero ME, Daniels DV, Makkar RR, et al. *The Lancet* 2025; Oct. 27: Published online.

TCT 2025 HUB

Visit the Hub at [ACC.org/TCT2025](https://www.acc.org/TCT2025) for all the coverage from the ACC.org Editorial team, including news stories, trial summaries, journal scans, video roundups and more.

## New Guidance Focused on Evaluation and Management of ATTR-CM

**A**n ACC Concise Clinical Guidance (CCG) report on “Transthyretin Cardiac Amyloidosis Evaluation and Management” provides updated strategies and best practices for clinicians, taking into account expanding disease-modifying therapies, heart failure (HF) therapies and potential future opportunities.

The CCG summarizes four key challenges associated with the diagnosis, evaluation and management of transthyretin amyloid cardiomyopathy (ATTR-CM), which is increasingly recognized as a cause of HF, particularly in older individuals. These challenges include a high index of suspicion, conducting an appropriate diagnostic evaluation, the need for an individualized management strategy and awareness of unanswered questions based on evolving evidence.

To help address these challenges and ensure care is taken “to avoid the most common diagnostic pitfalls,” the CCG includes an algorithm for cardiac amyloidosis. According to the Writing Committee, chaired by **Michelle M. Kittleson, MD, PhD, FACC**, the “first and most critical step ... is the exclusion of light chain amyloidosis.”

Guidance on individual selection and choice of ATTR-CM disease-modifying therapies is another key component of the new document, taking into account new therapies over the last decade, including mineralocorticoid receptor antagonists and sodium glucose-cotransporter 2 inhibitors, as well as specific disease-modifying therapies with transthyretin stabilizers (tafamidis and acoramidis) and the transthyretin silencer vutrisiran.

“The optimal time to start ATTR-CM disease-modifying therapy is at the earliest onset of symptomatic disease before significant end-organ dysfunction has ensued,” the CCG states. A flow chart is provided to help clinicians determine when it is too early for disease-modifying therapy; when disease-modifying therapy is appropriate; and when it may be possibly too late.

Looking ahead, the CCG explores future therapies, such as transthyretin silencing with gene editing and transthyretin depleters with monoclonal antibodies, which hold promise but await further study. Additionally, it highlights several key unanswered questions tied to initial therapy, combination therapy and HF management; monitoring disease progression; prevention of disease; and cost-effectiveness.

“Clinicians now have multiple options to preserve the quality of life and improve the survival of individuals living with ATTR-CM,” write the authors. “Although no studies presently demonstrate superiority of one agent over another, and although data are currently insufficient to recommend routine combination therapy and a change in therapy to mitigate disease progression, ongoing studies may help to clarify some of the unanswered questions to promote optimal care for individuals with ATTR-CM.”

**Scan the QR code** for the complete document published in *JACC*. ■



### DRIVING CONVERSATIONS AROUND THE NEW HYPERTENSION GUIDELINE

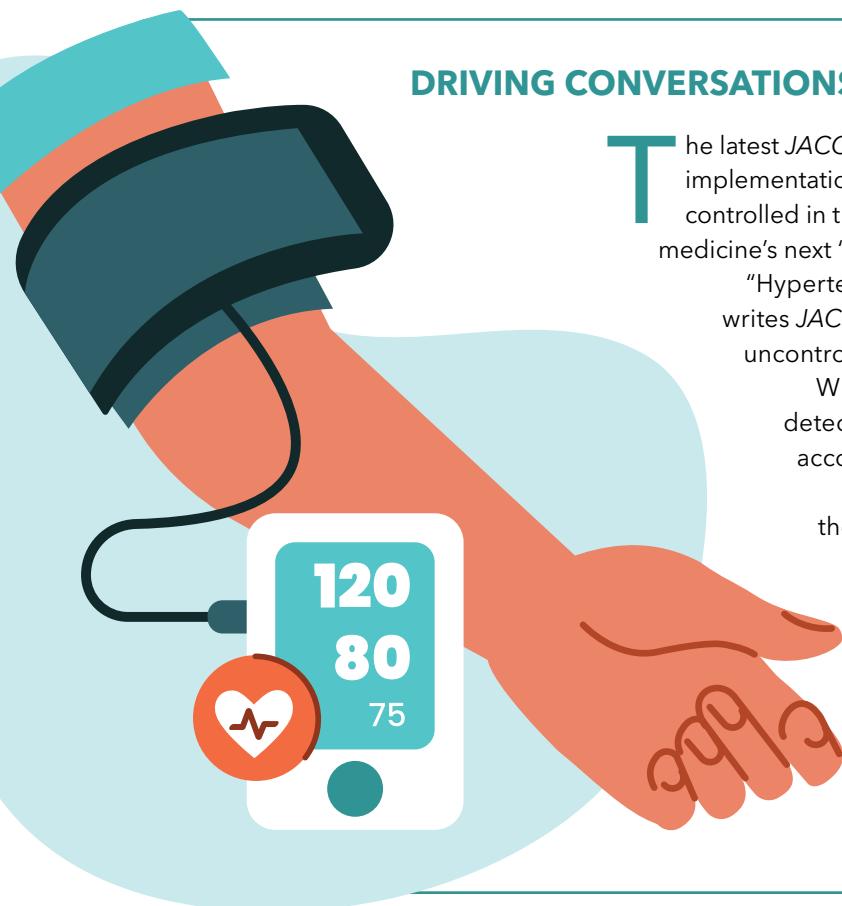
**T**he latest *JACC* focus issue on the 2025 ACC/AHA High Blood Pressure (BP) Guideline dives into the implementation failures that have led to hypertension going undiagnosed, untreated and inadequately controlled in the U.S. and charts a path forward where uncontrolled hypertension can become medicine’s next “never event.”

“Hypertension’s story is one of scientific triumph shadowed by implementation failure,” writes *JACC* Editor-in-Chief **Harlan M. Krumholz, MD, SM, FACC**, in an Editor’s Page. “Severe uncontrolled hypertension should be unthinkable in modern medicine.”

What’s the solution? Krumholz lays out a coordinated approach involving 1) reliable detection protocols, 2) simplified treatment algorithms, 3) affordable medications, 4) accountability systems and 5) patient and community empowerment.

The commentaries in this focus issue from leading hypertension authorities explore the evidence, rationale behind the latest recommendations and clinical application. In an accompanying Editor’s Note, **Erica S. Spatz, MD, MHS, FACC**, writes, “Our hope at *JACC* is that they challenge and refresh your thinking about hypertension...A reboot is overdue, and this guideline, together with the expert insights that accompany it, deliver exactly that.”

**Scan the QR code** to read the 24 viewpoints in this special issue of *JACC* designed to contextualize the guideline and make it easier to apply in practice. Remember to download the full guideline too. ■



# ACC LIVE FROM AHA 2025

AHA Annual Scientific Sessions

November 7-10, 2025

New Orleans, USA



The cardiovascular community came together for the AHA Annual Scientific Sessions from Nov. 7-10. The ACC was onsite covering late-breaking science and emerging trends, while the ACC Booth buzzed as a home base for members to connect, recharge and explore membership and educational opportunities. **JACC Journals** were also in the spotlight, with numerous simultaneous publications, and a special reception celebrating the cutting-edge research and collaboration driving the field forward. ■

4

The number of trials in the first Late-Breaking Science session focused on new cardiometabolic therapeutics.



Scan this QR code to read separate news summaries highlighting new research from **DR10624** and the **CORE-TIMI 72a/CORE-**

**TIMI 72b** trials, showing promise for patients with severe hypertriglyceridemia, as well as results from the **CRISPR-Cas9** study that made headlines in mainstream press.

Plus, scan this QR code for a video interview with ACC Vice President **Roxana Mehran, MD, FACC**, on session highlights.



~25

The total number of posters, cases and late-breaking or featured science published across **JACC Journals** during AHA 2025.



Scan the QR code to access all the papers.

400

The number of adults with uncontrolled hypertension and low antihypertensive medication adherence who were part of the BETTER-BP trial, the results of which were simultaneously published in **JACC**.



Scan the QR code to see if using a behavioral economics-based text incentive lottery improved adherence and outcomes.

Scan this QR code for a video interview with ACC Immediate Past President **Cathleen Biga, MSN, MACC**, addressing other BP-related trial results.



3

The number of years of follow-up associated with the OCEAN trial, which evaluated whether catheter ablation for atrial fibrillation eliminated the need for long-term anticoagulation with rivaroxaban for the prevention of stroke, systemic embolism and covert embolic stroke in high-risk patients.



Scan the QR code for the results.

Scan the QR code to watch a quick-take video with ACC Clinical Content Editor-in-Chief **Fred M. Kusumoto, MD, FACC**, and **Thomas Jared Bunch, MD**, on the trial.



90

The number of days some participants in the FOOD-HF trial received either medically-tailored meals or fresh produce boxes delivered conditionally or unconditionally following hospital readmissions for heart failure or emergency department visits. A control group did not receive meals or produce, but rather an equivalent monetary supplement. Learn the results and watch a video with **Carolyn S.P. Lam, MD**, at [ACC.org/AHA2025](https://acc.org/AHA2025).

## LOOKING FOR MORE?

Access Journal Scans, Trial Summaries, News Stories, Video Interviews and more at [ACC.org/AHA2025](https://acc.org/AHA2025). Special thanks to ACC Clinical Content Editor-in-Chief **Fred Kusumoto, MD, FACC**, **JACC** Editor-in-Chief **Harlan M. Krumholz, MD, FACC**, and **JACC** Editors **Rasha Al-Lamee, MD**, and **John Spertus, MD, FACC**, for their support of ACC Anywhere TV Daily Wrap-Up and Quick Take video coverage.

# Expanding the Cardiologist's Lens: The Urgency of PAD Management

By the time the patient entered the clinic, he was just days away from losing his leg and he had already been told amputation was inevitable. "He had ulcers on his toes, his foot was cold and nobody had checked his pulses," said **Craig M. Walker, MD**, medical director of the Cardiovascular Institute of the South in Lafayette, LA. He was speaking during a recent webinar on career pathways in vascular medicine hosted by ACC's Vascular Disease Section in collaboration with the Society for Vascular Medicine.

Fortunately, however, the man didn't lose his leg. "Within hours," Walker said, "we opened up his arteries, restored flow" and he still has his leg.

For Walker, a pioneer in peripheral interventions, the case epitomizes what's wrong – and what could be right – in the care of patients with peripheral artery disease (PAD).

"There's a massive population of patients who could be helped by cardiologists who already have the tools and the knowledge," he said. "We just have to recognize that PAD isn't separate from what we do – it is cardiovascular disease."

**Patients with late-stage lower-limb PAD are significantly likely to end up with an amputation. That, in turn, leads to a high mortality rate, with half of all patients who undergo a lower limb amputation dying within two to four years.**

## A Silent Epidemic

PAD is associated with an increased risk of amputation, myocardial infarction, stroke and death.<sup>1</sup> Yet it is "grossly underdiagnosed and undertreated," says **Pradeep Nair, MD, FACC**, an interventional cardiologist at the Cardiovascular Institute of the South. Thus, by the time patients are properly diagnosed they often have chronic limb-threatening ischemia (CLTI) and require amputation.

PAD affects 21 to 27 million Americans, according to revised estimates,<sup>2</sup> up substantially from previous estimates. An aging population coupled with the diabetes epidemic is driving the increase, Nair says.

There are also significant racial and ethnic disparities in PAD. Although Black and White

Americans develop PAD at similar rates, Blacks consistently experience worse outcomes, including amputation rates as much as 65% higher than Whites, and are also less likely to receive guideline-directed therapies than Whites. Additionally, while Blacks are more likely to present with advanced disease requiring urgent intervention, they receive revascularization less often. Even when receiving procedures, they face higher rates of complications and amputation within the first year.<sup>3</sup>

Numerous factors contribute to the disparity, including income level, insurance coverage and health care access. Another is access to specialists. "I have patients who drive three hours to see me," says **Cameron W. Donaldson, MD, FACC**, a vascular interventional cardiologist based in Portland, ME. His state and much of the South suffer from "vascular deserts," he says, where there are few specialists trained to treat vascular conditions. Such vascular deserts result in high rates of CLTI and amputation.<sup>4</sup>

Overall, the quality of care provided today remains poor. For instance, 60-80% of those with CLTI do not receive an angiogram before amputation, and in 50-70% there is no attempt

at revascularization. The result, Nair says, is "an epidemic of major amputations."

"A classic situation I see almost every week is a patient with CLTI who has a wound on their leg and who was seen by a cardiologist, but the patient didn't take off their shoes and socks or they just weren't examined," says Donaldson. Patients often don't mention a wound because they may not feel it, due to neuropathy. Even if they do, he notes, they are often told to go to the podiatrist or primary care doctor for care. "I see it regularly and it scares me."

Patients with late-stage lower-limb PAD are significantly likely to end up with an amputation. That, in turn, leads to a high mortality rate, with half of all patients who undergo a lower limb amputation dying within two to four years. In fact,

individuals are more likely to die within five years of an amputation than from any cancer except lung cancer, Nair says. In addition, a third of these patients end up in nursing homes. About half with a below-the-knee amputation and 75% of those with above-the-knee amputations never regain mobility.<sup>5</sup>

## Cardiologists Can Change the Trajectory

"Cardiologists see PAD every day," says Donaldson. "All of our patients have it. We're focused on the heart, but cardiovascular disease isn't just cardiac disease – it's cardiac and vascular." After all, he adds, the board certification is in cardiovascular disease.

Historically, vascular surgery was the domain that mainly treated PAD. But with only about 4,000 vascular surgeons in the U.S., there are far too few to meet the growing need. Moreover, they are trained to deal with the late-stage problems, like amputations and strokes.

"It's up to cardiologists to get to these patients before they reach that point," Donaldson says.

Despite the need for more vascular specialists, there is no American Board of Internal Medicine board certification in vascular medicine. Also, in training, there isn't a strong focus on PAD, and Nair recalls learning little about it during residency and cardiology fellowship.

## VASCULAR MEDICINE AND THE ACC

The ACC's Vascular Disease Member Section provides a forum for leadership, networking and education on this important topic. **Scan the QR code** to learn more and get involved.



Plus, don't miss focused sessions as part of the Vascular Medicine Learning Pathway at ACC.26 in March. Visit **ACCScientificSession.org** to register and plan your program.



“When you see cardiac or cerebrovascular disease, you should think PAD too. The treatment overlaps and cardiologists are already trained to manage it by improving blood pressure, cholesterol and diabetes, and by encouraging smoking cessation and exercise.”

Pradeep Nair, MD, FACC

Yet PAD is a critical marker of polyvascular disease. “When you see cardiac or cerebrovascular disease, you should think PAD too,” Nair says. “The treatment overlaps and cardiologists are already trained to manage it by improving blood pressure (BP), cholesterol and diabetes, and by encouraging smoking cessation and exercise.”

Basic bedside care is a large part of the solution, notes Nair. Look at the legs, check for hair loss and nonhealing wounds, and palpate pedal pulses. Screening can start with a simple ankle-brachial-index (ABI). The normal ABI range is 1.00 to 1.40. An ABI value of 0.91 to 0.99 is borderline and an ABI of  $\leq 0.90$  is abnormal. An ABI  $< 0.40$  signals a markedly increased risk of mortality.<sup>6</sup>

Importantly, do not rely on the patient to tell you what’s going on, says Nair. They do not always have pain and often the PAD is subclinical, which can be a marker for vascular disease in another area.

Plus, unlike the coronary artery, “we can easily check the pulse in a foot,” making this an easily accessible vascular conduit to evaluate for the absence of a pulse, which could be a marker of a much larger problem.

This requires a shift - rethinking routine practice to include assessment for PAD, says Donaldson. A full pulse exam, head to toe, is needed, along with listening to the heart and lungs.

In his practice, the medical staff is trained to have patients take off their shoes and socks so the doctor can easily examine the foot. They are also trained to measure BP in both arms. “Subclavian stenosis is quite common. If there is a blockage in one of the arteries in an arm, it will not be picked up unless a difference in BP is identified,” he highlights.

Whether general or more specialized, cardiologists should take the lead on PAD prevention and early diagnosis. They already manage risk factors that drive PAD. Getting those parameters under control can greatly improve limb as well as cardiovascular outcomes.

One challenge, Donaldson notes, is time. “Most cardiologists are so busy caring for heart failure, heart attacks and arrhythmias that they

don’t have five extra minutes to check pulses or ask about pain when walking.”

### The Knowledge Gap: A Barrier to Care

Another challenge is lack of awareness among the public and clinicians, particularly primary care physicians, about PAD.<sup>7,8</sup>

Indeed, multiple studies and reviews find that PAD is frequently underdiagnosed and undertreated, even though cardiologists are well-positioned to identify and manage it. This underappreciation is attributed to limited awareness, misconceptions about disease severity and insufficient training in vascular disease.<sup>7,9</sup>

Even surveys of cardiologists find a substantial proportion rate their knowledge of PAD risk reduction therapies as below average, and many are unfamiliar with management guidelines and racial disparities in the disease.<sup>10,11</sup>

Donaldson and Nair aren’t surprised. “It’s the neglected side of our training,” Donaldson says. “We owe it to our patients to treat the vascular problems they have everywhere - in the legs, brain and kidneys.”

Most interventional cardiologists already possess the imaging judgment, access techniques, and wire-and-catheter skills needed for many PAD interventions that can restore in-line flow, reduce tissue loss and improve function, Nair notes. “However, I strongly recommend they seek further training to understand the intricacies of peripheral vascular interventions.”

The field is quite dynamic, with new procedures and devices advancing the science. In 2023, the U.S. Food and Drug Administration approved a device that allows for deep vein arterialization to treat patients with CLTI whose only other option is amputation. The minimally invasive procedure creates a bypass from an artery to a deep vein in the foot to restore blood flow, potentially saving limbs from amputation.

The seminal clinical trial on the device showed that 76% of patients were able to avoid amputation and experienced progressive wound healing at six months.<sup>12</sup> Nair has seen it in his own practice, when he performed the procedure on a patient with a gangrenous foot. Two doctors told

### PAD EXAM CHECKLIST

- Examine legs for hair loss, nonhealing wounds
- Palpate pedal pulses, perform head-to-toe pulse exam
- Measure ankle-brachial index
- Ask patient about foot, leg pain
- Measure BP in both arms to screen for subclavian stenosis

the patient he needed an amputation, but Nair was able to save the foot. “And then with good wound care and follow up he was able to walk.”

The 2024 ACC/AHA guideline for lower extremity PAD diagnosis and management recommends team-based care, high-intensity statins, single antiplatelet therapy in most PAD patients, aggressive BP and diabetes management, smoking cessation and structured exercise therapy - and, when indicated, revascularization to prevent limb loss in CLTI and to improve quality of life in claudication.<sup>1</sup>

Indeed, studies find that geographic regions with quality vascular care can significantly reduce the risk of CLTI and the rate of amputations in patients with PAD.<sup>13,14</sup> The challenge is getting that care to patients early on.

“I feel strongly that education is the foundation for everything,” says Donaldson. “If we want to make a change in outcomes for our patients with PAD, we must start with education, starting with informing ourselves.” ■

References available with the online version of this article at [ACC.org/Cardiology](https://www.acc.org/Cardiology).

Editors’ Note: This is the first article in a two-part series on peripheral vascular disease. Watch for the second article on training pathways in vascular medicine for cardiologists in the next issue.

# hsCRP: A Promising Risk Assessment Tool

Inflammation plays a central role in the pathogenesis of atherosclerosis and cardiovascular disease.<sup>1</sup> Atherosclerosis in particular is an inflammatory process that involves endothelial dysfunction, leukocyte adhesion, plaque formation and eventual rupture.<sup>2</sup> T-lymphocytes contribute by degrading fibrous caps and reducing collagen synthesis. These inflammatory mechanisms drive atherosclerosis progression and elevate the risk of cardiovascular events such as myocardial infarction (MI) and coronary artery disease (CAD).

High-sensitivity C-reactive protein (hsCRP), the most studied and validated biomarker of systemic inflammation, is a particularly strong predictor of cardiovascular risk.<sup>2</sup> Elevated hsCRP is associated with future MI, stroke and cardiovascular disease death in both primary and secondary prevention populations, based on evidence from randomized controlled trials (RCTs) and observational studies.<sup>3-11</sup>

In primary prevention of atherosclerotic cardiovascular disease (ASCVD), an hsCRP  $\geq 2$  mg/L is considered a risk-enhancing factor in current guidelines.<sup>12</sup> hsCRP also predicts major adverse cardiovascular events (MACE) over the life course with 20 to 30 years of follow-up.<sup>11,13</sup> In patients with established ASCVD, elevated hsCRP is a marker of residual inflammatory risk and is a better predictor of future cardiovascular events and death than LDL-C.<sup>14,15</sup>

This body of evidence highlights the utility of hsCRP testing in cardiovascular risk assessment and management. The recently released ACC Scientific Statement on Inflammation and Cardiovascular Disease now recommends universal screening of hsCRP in both primary and secondary prevention populations.

SCAN THE QR CODE TO READ THE FULL STATEMENT.



## A Modifiable Risk Enhancer

It should be emphasized that hsCRP is modifiable and often can be lowered through behavioral and lifestyle interventions.<sup>15</sup> Smoking cessation reduces systemic inflammation. One study reported a 0.40 mg/L reduction in individuals with established cardiovascular disease,<sup>16</sup> where improvements in inflammation were observed the longer an individual remained smoke-free.<sup>17</sup> A meta-analysis showed that aerobic exercise reduces hsCRP by 0.59 mg/L in healthy adults and 0.34 mg/L in patients with cardiovascular disease.<sup>18</sup> These reductions were independent of BMI and relative adiposity, but greater

reductions were observed when both decreased concurrently with exercise intervention.<sup>19</sup>

Weight loss studies report a 0.25 mg/L decrease per 6.4 kg and an average reduction of 0.13 mg/L per kg.<sup>16,20</sup> Surgical weight loss interventions have resulted in some of the largest reductions of inflammation.<sup>20</sup>

The AHA's Life's Essential 8 (LE8) emphasizes the cumulative impact of multiple lifestyle and modifiable risk factors on cardiovascular health.<sup>21</sup> Multiple studies show that suboptimal LE8 metrics are associated with higher hsCRP levels.<sup>22,23</sup> For example, patients with a low LE8 score are nearly six-times more likely to have an hsCRP level  $>3$  mg/L.<sup>24</sup>

Heart-healthy dietary patterns can lower hsCRP. A meta-analysis of RCTs of the Mediterranean diet reported a 0.98 mg/L decrease in hsCRP.<sup>25</sup> High-risk patients had lower CRP levels on the diet plus olive oil than controls in PREDIMED.<sup>26</sup> A vegan diet was associated with a 0.54 mg/L reduction in hsCRP vs. a diet with plant plus animal products.<sup>27</sup> In EVADE CAD, patients randomized to a vegan diet had a 32% lower hsCRP.<sup>28</sup> Both high-fiber DASH and fiber-supplemented diets reduce CRP levels.<sup>29</sup> Another RCT showed that a high-fiber diet reduced hsCRP by 28%, comparable to treatment with lovastatin (20 mg/d).<sup>30</sup>

## Drugs to Reduce hsCRP

Statins reduce hsCRP to varying degrees.<sup>31,32</sup> For example, a study comparing simvastatin (40 mg/d) and atorvastatin (80 mg/d) reported hsCRP reductions of 4.3 mg/L and 3.7 mg/L, respectively.<sup>32</sup> Similar effects were reported with rosuvastatin and pravastatin.<sup>31,33</sup> Initiation or intensification of statin therapy should be considered in patients with persistently elevated hsCRP, irrespective of LDL-C level.<sup>15</sup> Bempedoic acid (BA) can also reduce hsCRP.<sup>9</sup> BA lowered LDL-C by 22.5% and hsCRP by 23.2% in patients with obesity ( $> \text{BMI } 30 \text{ kg/m}^2$ ).<sup>34</sup> Though ezetimibe alone does not lower serum CRP concentrations,<sup>33,35</sup> ezetimibe plus BA lowered hsCRP by 26-38%.<sup>35</sup>

Colchicine is known to reduce hsCRP, and recent meta-analyses showed that low-dose colchicine reduces MACE in patients with established cardiovascular disease.<sup>36-38</sup> However, in other RCTs low-dose colchicine did not reduce CV risk in patients after acute MI or stroke, and therefore may not be beneficial at the time of acute ischemia.<sup>39-41</sup> Even so, low-dose colchicine is now approved by the U.S. Food and Drug Administration and has a class 2b recommendation for secondary prevention in patients with CAD, and can be considered specifically for patients with chronic stable CAD.<sup>15,42-44</sup> Use of colchicine is generally safe but may cause mild diarrhea which typically resolves quickly, and is contraindicated in patients with

estimated GFR  $<45 \text{ mL/min/1.73m}^2$  or hepatic dysfunction.<sup>15,38,42,45</sup>

GLP-1 RAs reduce inflammation and cardiovascular risk.<sup>46</sup> The SELECT trial found a 20% risk reduction in MACE, 28% in MI and all-cause mortality by 19% with semaglutide.<sup>46</sup> Semaglutide lowered inflammation in patients with type 2 diabetes and overweight or obese.<sup>47,48</sup> In patients with heart failure with preserved ejection fraction and obesity, it reduced inflammation by 43.5% vs. 7.3% in the control group.<sup>49</sup>

In summary, universal screening of hsCRP in both primary and secondary prevention patients is now recommended.<sup>15</sup> Clinicians should consider hsCRP  $\geq 2$  mg/L as a risk enhancer when assessing ASCVD risk in primary prevention and may be particularly useful when a patient is deemed at intermediate risk.<sup>12,15</sup> For patients with persistently elevated hsCRP, initiate or intensify lipid-lowering therapy regardless of their LDL-C level. Consider colchicine for patients with chronic stable CAD to help treat residual inflammatory risk. Use of hsCRP testing can also help guide lifestyle recommendations and other pharmacologic interventions. ■

References available with the online version of this article at [ACC.org/Cardiology](https://www.acc.org/Cardiology).

This article was authored by **Dairina Hernandez Ortega, BS**, Inova Schar Heart and Vascular in Fairfax, VA, **Kamil Faridi, MD, MSc**, Yale School of Medicine in New Haven, CT, and **Lily Dastmalchi, DO, MA, FACC**, Inova Schar Heart and Vascular.



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- We currently have a full Cardiology Fellowship, an Interventional Cardiology Fellowship and the Lehigh Valley's first and only four-year medical school campus.

### **About St. Luke's University Health Network**

Founded in 1872, St. Luke's University Health Network (SLUHN) is a fully integrated, regional, non-profit network of more than 23,000 employees providing services at 16 campuses and 350+ outpatient sites. With annual net revenue of \$4 billion, the Network's service area includes eleven counties in two states: Lehigh, Northampton, Berks, Bucks, Carbon, Montgomery, Monroe, Schuylkill and Luzerne counties in Pennsylvania and Warren and Hunterdon counties in New Jersey. St. Luke's hospitals operate the largest network of trauma centers in Pennsylvania, with the Bethlehem Campus being home to St. Luke's Children's Hospital. Dedicated to advancing medical education, St. Luke's is the preeminent teaching hospital in central-eastern Pennsylvania. To learn more, visit [sluhn.org](http://sluhn.org).

Learn more about the greater Lehigh Valley at [discoverlehighvalley.com](http://discoverlehighvalley.com).

*\*We do not sponsor visas.*

## The Digital Operating Room: Patient-Specific Modeling For Optimal Structural Heart Outcomes

In a complex TAVR case, the analysis generated from the traditional preprocedural planning seemed reassuring. Annular dimensions appeared within range, coronary heights looked safe and the plan followed standard criteria. Yet when the patient's anatomy was modeled using the DASI Simulations computational modeling platform, a different story emerged. The dynamic interaction between the valve and calcified tissue revealed a previously overlooked risk that static measurements had missed. With this knowledge, the clinical team adapted their strategy and sent this patient to receive a surgical aortic valve replacement (SAVR) instead of a TAVR.

This case illustrates a broader problem: traditional planning tools reduce a living, deformable system to static numbers. The heart, however, is never static. Tissue compliance, calcium distribution and device expansion all interact in ways that imaging

snapshots cannot fully capture. Dynamic biomechanical simulation bridges this gap, transforming procedural planning from 2D measurements into a predictive view of real-world device and anatomy interaction.

### The Dynamic Difference

Traditional TAVR planning still relies heavily on static CT measurements, including annular diameters, coronary heights and sinus dimensions, which are frozen in 2D slices. These numbers help the team choose a device size, but they don't reveal how a stent frame will actually behave once it meets irregular calcium, compliant tissue and complex root geometry. In other words, a "one-size-fits-all" plan risks overlooking patient-specific realities.

Avoiding complications is challenging enough; however, what is increasingly at stake is the *quality* of the very first implant. As TAVR expands into younger populations,

the initial device must not only function reliably for decades but also preserve options for future interventions. Optimizing that first implant, both for durability and for lifetime management, has become a central focus in the evolution of TAVR planning.

Biomechanical computational models as developed at Georgia Institute of Technology can shift this paradigm. Instead of treating anatomy as a rigid structure, artificial intelligence (AI)-based simulations can model how a valve expands and interacts with surrounding tissue in 3D (**Figure 1**). This includes predicting how leaflets will displace, how the stent frame may deform and where contact pressures will peak. By capturing these dynamic factors, clinicians gain a preview of deployment that static planning cannot provide.

The value becomes clear in high-risk anatomical scenarios, such as bicuspid valves, bulky calcification, low coronary heights or valve-in-valve cases where millimeters matter. In these contexts, AI-based computational modeling offers not just better visualization but actionable insight, helping heart teams anticipate complications and tailor strategies before ever entering the cardiac catheterization lab.

**AI-based computational modeling offers not just better visualization but actionable insight, helping heart teams anticipate complications and tailor strategies before ever entering the cardiac catheterization lab.**



## Clinical Applications and Evidence

Over the past decade, TAVR has reshaped the treatment of aortic stenosis. What began as a lifeline for patients with inoperable conditions has now evolved into a frontline therapy, with large randomized clinical trials demonstrating strong results even in low-risk populations. By 2020, more than 400,000 patients worldwide had undergone TAVR, a number that continues to grow as the procedure proves less invasive and more accessible than open surgery.<sup>1</sup>

But success has not erased risk. Complications such as paravalvular leak (PVL), conduction disturbances requiring pacemaker implantation, valve thrombosis or even aortic root rupture remain concerns. As younger and healthier patients are treated, the stakes rise: these individuals will likely live decades with their prosthetic valves, making durability and complication avoidance paramount. Optimized valve sizing, precise positioning and careful selection are no longer optional; they are essential.

AI-based computational modeling has emerged as a mechanism to assist in refining these decisions. By simulating the actual deployment process, clinicians

As medicine shifts from population averages to patient-specific care, dynamic simulation exemplifies the kind of technology that will enable tailored strategies, extending not only to TAVR but to structural heart interventions of all kinds.

can better assess the risk of coronary obstruction, anticipate how calcified nodules might redirect frame expansion or determine whether a particular valve size will achieve maximum stent apposition while mitigating aortic root rupture in the sinuses. Studies evaluating these tools have shown encouraging predictive accuracy, suggesting they can help reduce adverse events and improve procedural success rates. The paradigm can be changed from solely identifying the size to personalizing for lifelong durability and complication reduction.

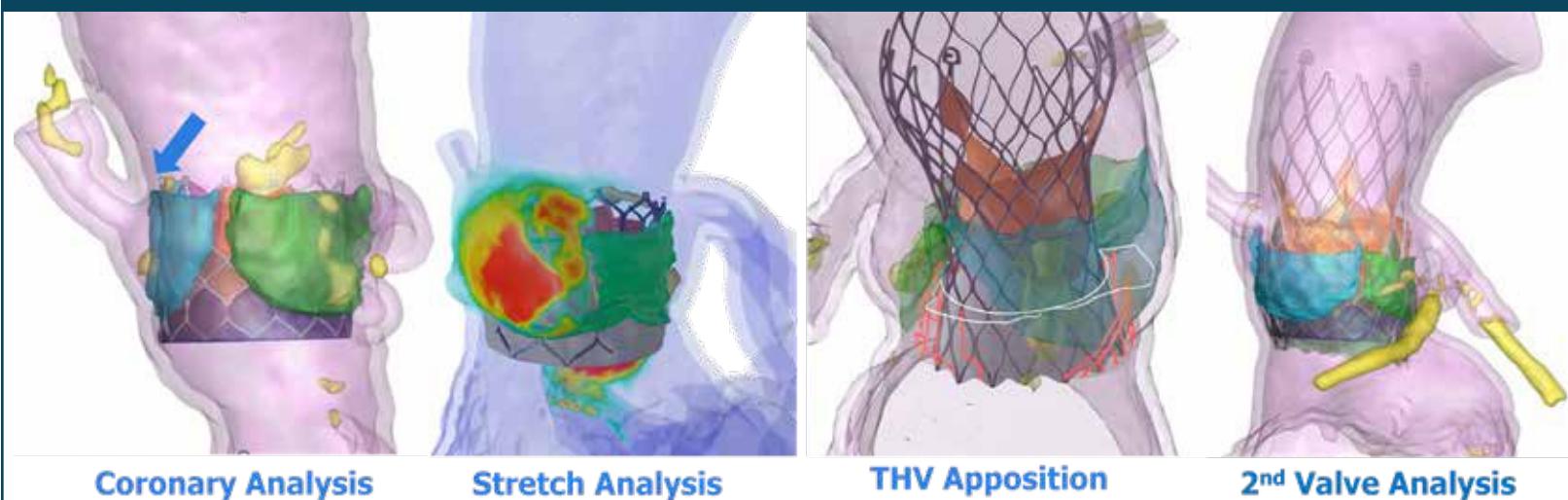
Recent studies highlight how simulations and computational modeling can enhance decision-making in the most complex anatomies. For example, Becker and colleagues evaluated the role of computational predictive modeling in bicuspid aortic valves, where asymmetric leaflets, heavy calcification and elliptical annuli often lead to unpredictable stent

expansion. Their work demonstrated that simulation could anticipate frame deformation and leaflet displacement patterns that standard CT planning could not, providing clinicians with a clearer view of how device-tissue interaction might compromise outcomes. Notably, the models highlighted risks of PVL and root injury, two complications that remain especially problematic in bicuspid interventions.<sup>2</sup>

Similarly, Holst, et al., applied these AI-based predictive simulations to patients at elevated risk of coronary obstruction during TAVR.<sup>3</sup> In this prospective series of 116 high-risk patients, computational modeling identified those most likely to encounter compromised coronary flow, guiding modifications such as bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction (BASILICA), chimney stenting or tailored depth of implant. Among patients predicted to be high risk, none experienced

Continued on the next page

Figure 1. AI-Based Predictive Modeling



AI-based predictive models provide a 3D quantitative picture to screen for coronary obstruction, root rupture via stretch analysis, PVL via transcatheter heart valve (THV) apposition analysis, and provide insights into a second valve inside the first valve.

Reprinted from *Annals of Thoracic Surgery*, 119(1), Holst K, Becker T, Magruder JT, et al. *Beyond Static Planning: Computational Predictive Modeling to Avoid Coronary Artery Occlusion in TAVR*. 145-151. Copyright 2025, with permission from Elsevier.

coronary occlusion when strategies were adjusted according to the simulation results (**Figure 2**).<sup>4</sup>

Together, these studies reinforce the central value of computational modeling: not simply visualizing anatomy, but forecasting the dynamic, patient-specific consequences of device deployment. AI models will soon be able to predict post TAVR gradient as well as the risk of thrombosis.<sup>5,6</sup> In doing so, simulation moves planning beyond static measurements toward proactive, individualized strategies that help mitigate catastrophic complications.

The need is amplified as TAVR expands into more hospitals and community settings. While access improves, variation in preprocedural planning quality raises concerns about inequities in care. A standardized simulation-driven approach could help ensure consistent planning rigor regardless of geography, supporting heart teams in both academic and regional centers.

**For new technologies to make a real difference, they must fit seamlessly into existing workflows.**

### Workflow Integration

For new technologies to make a real difference, they must fit seamlessly into existing workflows. Traditional finite element analysis has long been the gold standard in biomechanics. However, its complexity and heavy computational demands make it impractical for the real-time clinical decisions that a multidisciplinary cardiac care team must make.

Newer physics-based particle models, such as the U.S. Food and Drug Administration cleared PrecisionTAVI framework from DASI Simulations, that are now reimbursed by Medicare, are designed to overcome that barrier. These models run in minutes rather than days, while still capturing the essential valve-tissue mechanics that matter for planning. The result is a tool that fits within the typical timeline from CT acquisition to preprocedure heart team

conference. Teams can review the simulation results in conjunction with their current preplanning analysis to create a more holistic picture of the patient's unique anatomy.

### Practice Implications

Incorporating simulations into preprocedural planning is not meant to replace clinical judgment - it's about enhancing it. By quantifying likely deformation, contact pressures and flow pathways, biomechanical modeling provides the heart team with a richer evidence base for discussion. Communicating these insights to patients can also enhance shared decision-making, as risks and trade-offs become more visible rather than abstract.

For hospitals, reducing complications has both clinical and economic impact. TAVR remains one of the costliest procedures in cardiovascular medicine, with valve prostheses alone accounting for the majority of reimbursement. Each avoided complication not only spares patients from morbidity but also helps

institutions optimize resource use in an era of tightening margins.

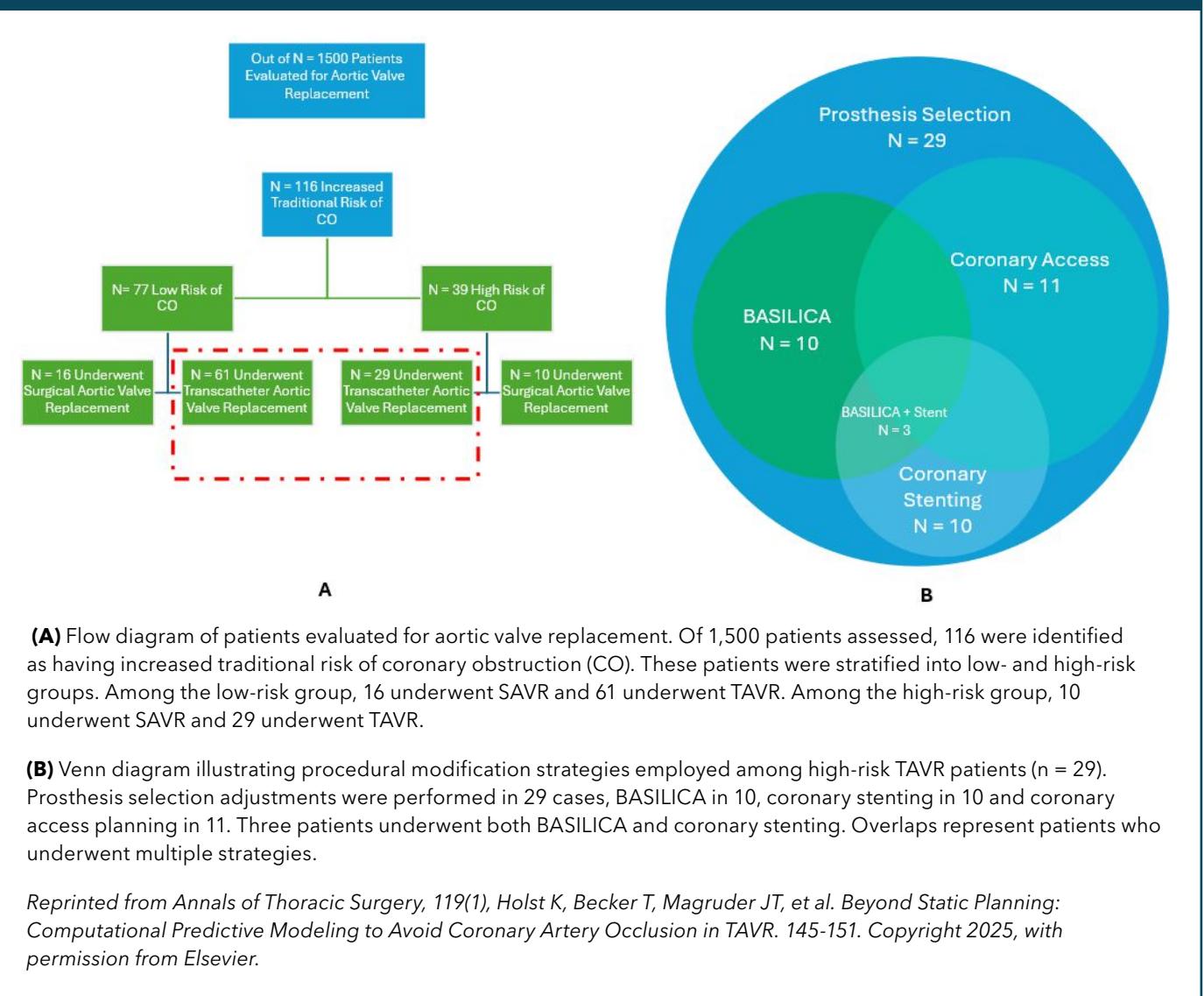
### Future Directions

The future of TAVR planning lies in making simulation smarter and faster. Coupling particle-based biomechanics with machine learning opens the door to instant predictions at the point of care. Beyond preprocedure planning, these models may soon guide operators during the intervention itself, adjusting in real time as deployment unfolds.

More broadly, the trajectory points toward personalization. As medicine shifts from population averages to patient-specific care, dynamic simulation exemplifies the kind of technology that will enable tailored strategies, extending not only to TAVR but to structural heart interventions of all kinds. ■

References available with the online version of this article at [ACC.org/Cardiology](https://www.acc.org/Cardiology).

**Figure 2. Prospective Series Using AI-Based Predictive Simulation**



This article was authored by **Taylor Becker, PhD**, Department of Biomedical Sciences, The Ohio State University, Columbus, OH, and **Lakshmi Prasad Dasi, PhD, FACC**, Department of Biomedical Engineering, Georgia Institute of Technology and Emory University, Atlanta, GA, and founder and chief technology officer of DASI Simulations.



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# FEAR THE FOMO: WHY YOU CAN'T MISS ACC.26

Get ready for the year's biggest gathering of cardiovascular professionals - where discovery meets culture and every session, conversation and connection counts

## THE SCIENCE YOU'LL BE TALKING ABOUT

If it's happening in cardiology, it's happening at ACC.26! From groundbreaking late-breaking clinical trials to featured clinical research shaping the future of cardiovascular medicine, ACC.26 is where the biggest discoveries make their debut. Be among the first to hear the data that will define tomorrow's practice, offering new insights into emerging therapies and long-term outcomes from established treatments.

The meeting will also provide more opportunities to dive deep into the newest clinical guidelines and join discussions with leading experts on topics ranging from real-world best practices to navigating challenges with implementation. Plus, don't miss the opportunity to explore hot topics like critical care cardiology, sports cardiology and care of the oncology patient as part of new pre-conference sessions taking place on Friday, March 27.

Expect interactive educational sessions, from Fireside Chats to Town Halls, where trending topics like artificial intelligence in cardiovascular care - the focus of this year's Intensive and a thread woven throughout the clinical pathways - as well as digital health advancements, prevention-focused tools, and technologies driving more equitable outcomes will take center stage.

The future of cardiovascular care will be unfolding in real time, so make sure you're there to see it first.

## CONNECTIONS THAT POWER PROGRESS

From meaningful conversations to memorable moments, ACC.26 is where collaboration comes to life. Network with peers and mentors in the **Lounge & Learn Pavilion**, home to interactive sessions, informal meetups, and the annual Career Fair connecting talent and opportunity. The **Member Lounge** is back this year, offering a dedicated space for FACC and AACC members to recharge, reconnect and build relationships that last well beyond the meeting. Looking for a team challenge? Test your problem-solving skills in two Escape Rooms in the **Personalized Skills Zone**.

The energy continues into the **Expo Hall**, where opportunities abound to connect with innovators and changemakers. Whether it's the **Health Equity Hub**, **Future Hub** or other Learning Destinations, conversations around equitable care, digital health and emerging technologies are key to shaping the next era of cardiovascular medicine. Plus, don't miss the **Engage Stage**, home to the ever-popular FIT Jeopardy competition.

The connections built throughout ACC.26 will come full circle during Monday's revamped **Convocation and Closing Ceremony**. Stay through the end to celebrate the newest FACC and AACC members, honor the newest Distinguished Awardees, revisit the week's most impactful science, and welcome the next ACC President - together marking the start of another year of progress in cardiovascular care.

## "FOMO MOMENTS NOT TO MISS"

- ! NEW Focused Pre-Conference Sessions
- ! Opening Showcase and Keynotes
- ! ACC.26 Expo
- ! Late-Breaking Clinical Trials and Featured Clinical Research
- ! "Beat the Clot," "PHeudin' on Bourbon Street" and Other Clinical Games in the Gameshow Room
- ! Three-Part AI Intensive
- ! Escape Room Team Challenges in the Personalized Skills Zone
- ! Convocation and Closing Ceremony

## THE EXPERIENCE - THE CITY. THE VIBE. THE YOU.

"Laissez les bons temps rouler!" ACC.26 is more than a meeting, it's an experience. Between sessions, step out and soak up the unmistakable rhythm of New Orleans! From vibrant art and culture to unforgettable food and hospitality, New Orleans offers the perfect backdrop to connect, recharge and celebrate cardiovascular care in the heart of the city.

### 5 Ways to Make the Most of Your Experience:

- 1 **Follow the Music:** Catch a live jazz performance on Frenchmen Street or Jackson Square or join a second line.
- 2 **Taste the Tradition:** Start your morning with beignets and chicory coffee.
- 3 **Explore the Streets:** From the French Quarter to Royal Street, street art, galleries and historic charm await.
- 4 **Dine Like a Local:** Sample gumbo, jambalaya or oysters at a classic Creole spot.
- 5 **Experience the Nightlife:** From Bourbon Street energy to jazz lounges, network and unwind with colleagues and/or new friends

## YOUR NO-FOMO CHECKLIST

- ✓ Register early and reserve your hotel. Advance registration closes Feb. 11.
- ✓ Book your flight! Remember to plan your travel time around Friday's pre-conference events and Monday's Convocation and Closing Ceremony.
- ✓ Follow @ACCinTouch for sneak peeks and tag #ACC25 to join the buzz.

**Fear the FOMO? Don't. Be There.**



Scan the QR code to get started.

## JUST ANNOUNCED: ACC.26 KEYNOTES



### 57TH ANNUAL LOUIS F. BISHOP KEYNOTE

Saturday, March 28  
*Scaling AI in Cardiology: Moving From Paper and Podium to Product*  
Presented by **Mintu Turakhia, MD, MS**



### ACC.26 DAN G. MCNAMARA KEYNOTE

Saturday, March 28  
*Looking Back, Moving Forward: The Evolution of ACHD*  
Presented by **Carole A. Warnes, MD, FACC**



### ACC.26 JAMES T. DOVE KEYNOTE

Saturday, March 28  
*Power in Partnership: Aligning Teams and Data For Cardiovascular Impact*  
Presented by **Cathleen Biga, MSN, MACC**



### DOUGLAS P. ZIPES DISTINGUISHED YOUNG SCIENTIST AWARD KEYNOTE

Sunday, March 29  
*The Future of AI in Cardiology and Bottlenecks Translating Research to Clinical Care*  
Presented by **Rohan Khera, MD, MS, FACC**



### 2026 EUGENE BRAUNWALD KEYNOTE

Sunday, March 29  
Presented by **Paul A. Friedman, MD**

# Lipoprotein(a): An Independent Risk Factor For CV Disease

By Debra L. Beck, MSc

**L**ipoprotein(a) [Lp(a)] has evolved from a biochemical curiosity to a central player in cardiovascular risk assessment, with elevated levels affecting approximately 1.5 billion people worldwide as an independent and causal risk factor for atherosclerotic cardiovascular disease (ASCVD) and calcific aortic valve disease.<sup>1,2</sup>

## Pathophysiology and Genetics

Lp(a) is a low-density lipoprotein (LDL) particle to which apolipoprotein(a) [apo(a)] is covalently bound. The presence of apo(a) confers proatherogenic, proinflammatory and prothrombotic properties. Plasma concentrations of Lp(a) are approximately 70-90% genetically determined and remain remarkably stable over an individual's lifetime.<sup>1,2</sup>

Ethnic differences are substantial, with concentrations lowest in people from China, Europe and Southeast Asia, intermediate in people from South Asia, and highest in Blacks. Concentrations are 17% higher in postmenopausal women than in men.<sup>2</sup>

## Epidemiology and CV Risk

A robust body of observational and Mendelian randomization data establishes a causal relationship between elevated Lp(a) and ASCVD, ischemic stroke and calcific aortic valve stenosis (CAVS).<sup>3</sup>

A landmark 2024 study from the Women's Health Study of nearly 28,000 initially healthy U.S. women with 30-year follow-up showed that baseline Lp(a) levels in the highest quintile conferred an adjusted hazard ratio of 1.33 (95% CI, 1.21-1.47) for first major cardiovascular events (myocardial infarction, coronary revascularization, stroke or death from cardiovascular causes) vs. the lowest quintile; this effect was independent of hsCRP and LDL-C.<sup>4</sup> The results underscore that Lp(a) adds long-term prognostic information, even when measured once mid-life.

Recent secondary-prevention data further show that in more than 270,000 patients with established ASCVD, higher Lp(a) levels were associated with continuously increasing risk of recurrent ASCVD.<sup>5</sup> Additionally, Lp(a) has been implicated in the progression of CAVS via deposition of oxidized phospholipids that fuels inflammation and calcification in the valve.<sup>6</sup>

Together, these data point to a continuous risk relationship with Lp(a) with no clear evidence of a threshold effect.<sup>7</sup> Also, Lp(a) confers risk independent of traditional ASCVD risk factors, including LDL-C and blood pressure.

Because Lp(a) levels are genetically determined and stable over time, a one-time measurement is sufficient for most patients. The 2024 focused update from the National Lipid Association recommends measurement of Lp(a) levels at least once in every adult, with individuals having Lp(a) levels  $\geq 50$  mg/dL considered high risk.

## An Evolving Therapeutic Landscape

Individuals with Lp(a) levels of 50 mg/dL or higher are at greater risk for ASCVD events and should be treated with lifestyle management such as smoking cessation, physical activity and weight



loss, and should receive treatment to lower blood pressure, LDL-C, glucose and other cardiovascular risk factors as recommended by guidelines.<sup>7</sup>

Statins do not meaningfully reduce Lp(a) and may even slightly increase it in some people. PCSK9 inhibitors lower LDL-C by up to 60% and Lp(a) by up to 30% but have not been tested in individuals with high Lp(a) and are not indicated for Lp(a) reduction. Lipoprotein apheresis can reduce Lp(a) by about 35% but is resource-intensive and reserved for extreme cases.

The therapeutic horizon has shifted dramatically with the recent development of RNA-based therapies:

- **Lepodisiran:** In the phase 2 ALPACA trial presented at ACC.25, a single 400 mg dose achieved a mean Lp(a) reduction of 93.9% at day 180, with this reduction persisting >90% at 360 days after a single injection.<sup>8</sup> No safety signals were revealed. A phase 3 cardiovascular outcomes trial, ACCLAIM-Lp(a), is currently enrolling.
- **Olpasiran and Zerlasiran:** These siRNA agents have achieved >80-90% sustained reduction in Lp(a) with dosing every 12-24 weeks.
- **Pelacarsen:** Data from a Phase 2 study showed this antisense oligonucleotide reduced Lp(a) levels below the recommended threshold of risk for cardiovascular disease events (<50 mg/dL) in 98% of participants.<sup>9</sup> Topline results from the Lp(a) HORIZON trial are expected soon.

Other Lp(a)-lowering agents have demonstrated encouraging results in clinical studies, notably muvalaplin, an oral small molecule inhibitor, which reduced Lp(a) by 86% in a recent phase 2 trial.<sup>10</sup>

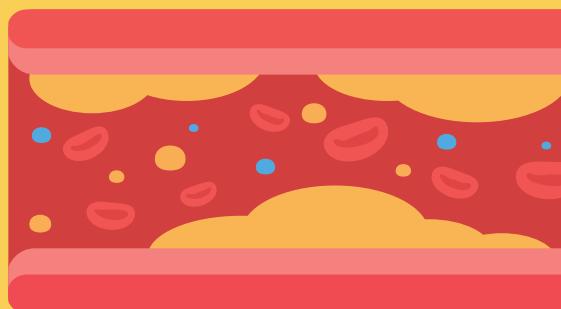
While the magnitude and durability of the reductions seen are striking, no published outcome trial to date has definitively shown that Lp(a) lowering reduces major cardiovascular events. The key question remains unanswered: will reducing Lp(a) translate into improved clinical outcomes? Until then, cardiologists must optimize standard-of-care therapies and counsel patients accordingly. ■

## DYSLIPIDEMIA LEARNING PATHWAY AT ACC.26

Plan now to attend ACC.26 from March 28-30 in New Orleans and make the most of this informative and interactive Learning Pathway. Visit [ACCScientificSession.org](https://accscientificsession.org) to register today!

## DON'T LET LP(a) BE A MYSTERY - UNCOVER IT AT ACC.26!

Don't know your levels? Free nonfasting lipid screening for Lp(a), along with hs-CRP, will be available at the ACC.26 Expo, near the Relax & Recharge Lounge. Add it to your list of must-do activities while in New Orleans in March!



# Cardio-Obstetrics Essentials: Advancing Care For Women's Heart Health

**C**ardiovascular disease is now the leading cause of maternal mortality in the U.S., and rates of maternal morbidity and mortality continue to climb driven by preexisting heart conditions and risk factors linked to advancing maternal age.

To address this urgent challenge, the ACC's *Cardio-Obstetrics Essentials: Team-Based Management of Cardiovascular Disease and Pregnancy*, led by Course Chair **Natalie Bello, MD, MPH, FACC**, and Vice Chair **Deirdre J. Mattina, MD, FACC**, provided clinicians with an interprofessional deep dive into this evolving field. Held in October at ACC's Heart House headquarters in Washington, DC, and virtually, the course focused on equipping clinicians with strategies for better diagnosis, risk assessment and treatment of patients of childbearing age. Key takeaways from the meeting include:

- 1 Maternal morbidity and mortality in the U.S. remain unacceptably high, with cardiovascular disease being a major contributor to adverse pregnancy outcomes. Combating the maternal health crisis will require expansion of pregnancy heart teams, addressing racial/ethnic disparities in care, and mandated insurance coverage for one year postpartum.
- 2 Technology can and should be utilized to improve access to care for pregnant and postpartum patients. Remote blood pressure monitoring, telehealth and electronic medical record (EMR) dashboards as well as shared medical appointments are among the options for leveraging out-of-hospital care.
- 3 Two risk stratification tools, mWHO 2.0 and CARPREG II, can help guide preconception counseling and pregnancy management of cardio-obstetric patients. However, it's important to keep in mind that while risk stratification is essential to informed

## CardioOB Resources



Scan the QR code for the latest CardioObstetrics-related science published across *JACC Journals*.



Scan the QR code to learn more about the ACC's Reproductive Health & Cardio-Obstetrics Member Section. Already a member? Make sure to take advantage of Section resources, including a comprehensive webinar library and links to the Postpartum Hypertension Clinic Development Toolkit.



Scan the QR code to watch sessions from **Cardio-Obstetrics Essentials: Team-Based Management of Cardiovascular Disease and Pregnancy 2025** with the ACC Anywhere video library. Subscription is required.

decision-making, scores do not always accurately reflect risk in complex patients. An individualized, multidisciplinary approach should be employed for every patient.

- 4 Preconception counseling is critical for women with cardiovascular disease because it allows clinicians to assess risk, optimize heart health and develop individualized care plans before pregnancy. Preconception counseling should include discussions around:
  - Recommendations on gestational weight gain based on prepregnancy weight
  - Physical activity recommendations that are SMART (Specific, Measurable, Achievable, Relevant and Time-Bound)
  - Adherence to a Mediterranean-style diet
  - Use of aspirin for preeclampsia prophylaxis
  - Management of chronic hypertension in pregnancy to a goal <140/90 mm Hg.

- 5 Understanding hemodynamic shifts across pregnancy, delivery and postpartum is essential to minimize acute maternal decompensation, especially in patients with adult congenital heart disease. A well-crafted delivery plan agreed upon by the pregnancy heart team, including an anesthesiologist, should be documented in the EMR and include postdelivery monitoring specifications and contingencies. ■

This article was authored by **Tahreem Iqbal, MD**, a fellow in Adult General Cardiology, Rutgers Robert Wood Johnson Medical School, New Brunswick, NJ, and **Tracey Crooks, MD**, fellow in Adult Congenital Heart Disease, University of Colorado, Denver.

## START STRONG WITH ACC.26 PRE-CONFERENCE SESSIONS!

**K**ick off your ACC.26 experience in New Orleans with a full day of immersive learning on Friday, March 27 from 10 a.m. to 6 p.m. CT.

Choose from five focused pre-conference sessions that offer deep dives into key areas of cardiovascular care. Led by world-renowned experts in an intimate, interactive setting, sessions will focus on the following topics: the cardiovascular care of oncology patients, care of the athletic heart and critical care cardiology essentials.

Plus, don't miss an NP/PA CCK Exam Review and a *JACC* Educational Workshop. Add a pre-conference to your registration with the ACC.26 PLUS Package and make the most of your experience! Advance Registration is open until Feb. 11. **Scan the QR code** to register now. ■

# ACC.26



**MARCH**  
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# TCT 2025: Transformative Trials Redefining Cardiovascular Intervention

The Transcatheter Cardiovascular Therapeutics (TCT) 2025 meeting in San Francisco delivered one of the most energizing late-breaking clinical trial lineups in recent memory. From coronary interventions to valve therapies and pulmonary embolism (PE) care, this year's data painted a vision of precision, restraint and personalization in interventional cardiology.

## Coronary Intervention: Less Metal, More Medicine

### Drug-Coated Balloons Move to Center Stage

Among the most talked-about sessions was the rise of sirolimus-eluting drug-coated balloons (DCBs). In the **SELUTION DeNovo** trial, more than 3,000 patients were randomized to a DCB-first approach vs. conventional drug-eluting stent (DES) implantation for de novo lesions. At one year, the DCB strategy proved noninferior to DES for target-vessel failure, signaling a genuine paradigm shift.

Clinically, this means operators may increasingly favor a “leave-nothing-behind” approach – particularly for small vessels, bifurcations and side branches – where stent-related late events can be avoided. Rather than a full-scale stent replacement, the field is moving toward selective use based on lesion morphology and vessel size.

In parallel, **SELUTION4ISR** confirmed that sirolimus DCBs matched repeat DES implantation for in-stent restenosis. The ability to treat restenosis without adding more metal layers reinforces the appeal of DCBs as a clean, vessel-preserving therapy.

### Calcified Lesions: Simpler Tools, Similar Outcomes

The **VICTORY** trial compared super-high-pressure noncompliant balloons to intravascular lithotripsy (IVL) in heavily calcified lesions. The results showed noninferiority for stent expansion and procedural success.

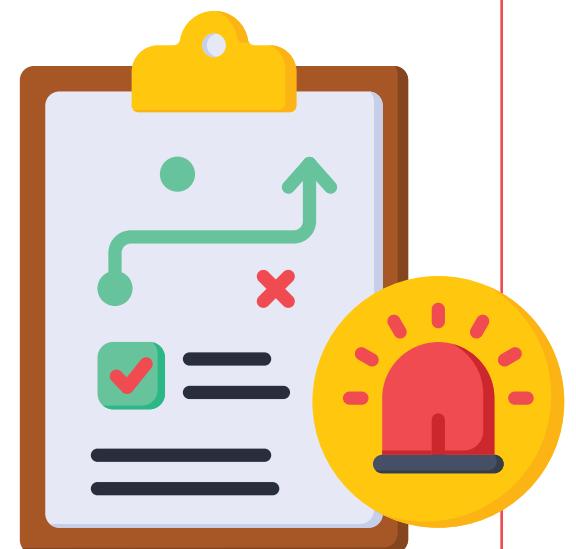
The takeaway is pragmatic: IVL remains invaluable for extreme calcium, but well-executed high-pressure ballooning can achieve excellent outcomes at lower cost and with broader availability. Institutions facing budget constraints may adopt a stepwise strategy – balloon preparation first, IVL reserved for resistant lesions.

### Post-CABG PCI: Conventional Wisdom Challenged

For decades, guidelines have favored native-vessel PCI over graft intervention when bypasses fail. The **PROCTOR** trial defied this dogma. Patients treated with saphenous vein graft (SVG) PCI had fewer major adverse cardiac events than those undergoing native-vessel PCI, driven by less procedural myocardial infarction (MI) and lower repeat revascularization rates. If durability holds up, this will prompt guideline reevaluation and more nuanced, anatomy-driven decisions within the Heart Team framework.

## CLINICAL IMPLICATIONS: WHAT CHANGES ON MONDAY MORNING

- 1. A shift toward DCB-first PCI.** Operators will adopt DCBs for small vessels and in-stent restenosis, reserving stents for bailout or anatomy that truly requires scaffolding. Hospitals should refine protocols for lesion preparation, balloon sizing and postprocedure antiplatelet duration.
- 2. A cost-savvy calcium strategy.** After VICTORY, expect a stepwise lesion-modification algorithm – balloon first, IVL if needed – without compromising outcomes.
- 3. Rewriting post-CABG playbooks.** SVG PCI may become the preferred approach when feasible, challenging long-standing biases against graft intervention.
- 4. STEMI revascularization timing refined.** Immediate nonculprit intervention adds no clear benefit; staged evaluation using physiology or CMR is entirely appropriate.
- 5. Mechanism-driven MINOCA care.** A dedicated diagnostic algorithm should become part of ACS protocols, ensuring patients receive targeted therapy rather than blanket treatment.
- 6. Structural heart maturity.** Seven-year TAVR durability data settle nerves about long-term outcomes. For severe MAC, TMVR is now viable, and the tricuspid field is rapidly evolving.
- 7. PE intervention mainstreamed.** STORM-PE's findings will accelerate PE service lines and ensure mechanical thrombectomy becomes a core hospital capability.
- 8. Imaging as the new frontier.** AI-QCT and bioadaptive implants symbolize the shift toward biologic precision and preventive cardiology.





### **Physiology-Guided STEMI Care: A Reality Check**

The **iMODERN** trial tested immediate, iFR-guided multivessel revascularization in STEMI against deferred, CMR-guided staged care. The study found no superiority for the immediate strategy. The implication: for stable patients, deferral with functional imaging remains a sound, patient-centric path. It reinforces that completeness of revascularization matters – but timing and context matter just as much.

### **Microvascular Obstruction: The Search Continues**

**STRIVE** explored intracoronary low-dose alteplase during primary PCI for large-territory STEMI. Disappointingly, there was no reduction in microvascular obstruction or improvement in outcomes – and a hint of higher arrhythmia risk. The message: fibrinolytics are not the answer, and new anti-microvascular injury approaches are still needed.

### **MINOCA: The Power of a Precise Diagnosis**

The **PROMISE** trial, the first randomized study in myocardial infarction with nonobstructive coronary arteries (MINOCA), showed that an etiology-guided strategy after comprehensive imaging improved angina and diagnostic accuracy. The results validate systematic work-ups – combining CMR, intracoronary imaging and vasoreactivity testing – before empiric therapy. MINOCA management must be mechanism-based, not one-size-fits-all.

### **Structural Heart Disease: Reassurance and Expansion**

#### **TAVR Durability Reaches the 7 Year Mark**

The much-anticipated seven-year outcomes from **PARTNER 3** finally addressed long-term durability concerns. In low-risk aortic stenosis, transcatheter and surgical valve replacement showed similar survival, stroke and rehospitalization rates, as well as comparable valve durability.

This provides critical reassurance that TAVR can serve not only as a bridge for the elderly but also as a legitimate long-term solution for younger, low-risk patients – provided lifetime

management and potential future interventions are carefully planned.

#### **TMVR in Severe MAC: A New Lifeline**

For patients with severe mitral annular calcification, historically deemed “no-option,” the **SUMMIT-MAC** trial using the Tendyne system demonstrated high procedural success, sustained MR reduction and significant symptomatic improvement at one year. Apical access bleeding remains the main procedural challenge, but this marks a meaningful therapeutic advance for a group previously relegated to palliation.

#### **Tricuspid Therapies: Gaining Confidence**

Expanded data from TEER and replacement systems continue to affirm safety, durable symptom improvement and growing operator experience. Patient selection remains key: right ventricular function, pulmonary pressures and annular geometry determine success. The once-ignored tricuspid valve is now firmly in the spotlight, with technology and evidence rapidly catching up.

### **Vascular and PE Interventions**

#### **STORM-PE: Mechanical Intervention Arrives**

Perhaps the most practice-changing vascular trial was **STORM-PE**, comparing catheter thrombectomy with anticoagulation alone in intermediate-risk PE. Thrombectomy significantly reduced clinical deterioration and improved right ventricular function without excess bleeding.

This establishes a new therapeutic benchmark: for selected patients, removing clot matters. Hospitals are now expected to develop 24/7 Pulmonary Embolism Response Teams (PERTs) and ready access to thrombectomy devices. For interventionalists, PE care is becoming an integral service line, not a niche procedure.

### **Disruptive Technologies and Imaging Innovation**

#### **Bioadaptors: The Next Evolution Beyond DES**

The **INFINITY-SWEDEHEART** trial introduced the DynamX Bioadaptor – an implant that

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functions like a DES initially but gradually unlocks as the polymer resorbs, allowing the vessel to regain natural motion. From six to 24 months, target-lesion failure rates dropped nearly by half compared with conventional DES, especially in acute coronary syndrome.

This “adaptive scaffolding” approach could redefine durability and late-event profiles, offering freedom from the permanent metallic cage while maintaining early antiproliferative benefit.

### **AI-Guided Plaque Imaging: Predicting the Future**

Advances in quantitative coronary CT angiography using artificial intelligence (AI) showcased the power of imaging-based prevention. By quantifying noncalcified and high-risk plaque, AI-QCT can reclassify risk beyond luminal stenosis. In practical terms, clinicians will be able to identify patients with dangerous plaque biology earlier and intervene medically before events occur.

The broader theme emerging from TCT 2025 is not just treating obstruction but predicting and preventing it. ■



This article was authored by **M. Chadi Alraies, MD, FACC**, medical director of the cardiac catheterization laboratory, cardiac rehabilitation, and interventional cardiology research at Detroit Medical Center, Harper University Hospital, in Michigan.

# Maximizing Recovery: Cardiac Rehab in Contemporary CV Care

By Debra L Beck, MSc

Cardiac rehab (CR) remains one of the most underutilized interventions in cardiovascular medicine despite overwhelming evidence that it saves lives, improves quality of life and is cost effective. While ACC/AHA performance measures and numerous clinical practice guidelines consistently recommend CR as a Class I indication for patients following acute coronary syndromes, cardiac procedures and heart failure (HF) diagnoses, referral rates fail to reach even 25% among Medicare beneficiaries.<sup>1</sup> This gap represents a significant missed opportunity to improve patient outcomes and reduce health care costs.

Modern CR programs employ a multidisciplinary approach that addresses the complex interplay of factors contributing to cardiovascular risk, creating synergistic effects that exceed the sum of individual components. Importantly, they should be tailored to each patient's needs.

“Cardiac rehab is a multicomponent approach that can help us bridge the gaps in care that we see in some groups because it focuses on a broader perspective of management, truly treating the patient holistically.”

Daniel E. Forman, MD, FACC

“Good cardiac rehab today is individualized to the patient. This means that you do something different for the 80-year-old woman who just had her chest cracked, who's frail and has a bad hip and needs to optimize her recovery, compared to the 35-year-old spontaneous coronary artery dissection patient who was running a few weeks ago and now needs some help to regain confidence in her body,” says **Sharonne N. Hayes, MD, FACC**, a cardiologist from the Mayo Clinic in Rochester, MN, and the founder of their Women's Heart Clinic. “But if the patients aren't referred, they get none of that.”

Why do we consistently fall short in connecting our patients to this lifesaving intervention? And how can we bridge this implementation gap to ensure our patients receive the comprehensive care they deserve?

## The Evidence Base: Beyond Question

The research supporting the benefits of exercise-based CR is well established. A contemporary update of the evidence base in 2023 by Dibben, et al., included 85 randomized controlled trials involving 23,430 participants with a median

12-month follow-up in a meta-analysis.<sup>2</sup> They showed that, overall, exercise-based CR was associated with a significant 26% risk reduction in cardiovascular mortality (number needed to treat [NNT], 37), a 23% risk reduction in hospitalizations (NNT, 37) and an 18% risk reduction in myocardial infarction (MI) (NNT, 100).

There was also some evidence that CR improved health-related quality of life and was cost-effective. No significant difference in treatment effects was found across different patient groups, CR delivery models, doses, follow-up or risk of bias.

“Some cardiologists still think of rehab as something needed to get patients back on their feet and moving after the procedural burden of CABG, but not as something truly fundamental to treating coronary artery disease, especially compared to a stent, antiplatelets and a statin,” opines **Daniel E. Forman, MD, FACC**, a geriatrician-cardiologist at the University of Pittsburgh Medical Center and VA Pittsburgh

Healthcare System. Forman, who has directed CR programs for two decades in Pittsburgh and Boston, notes that referral rates are worse after PCI than cardiac surgery.

This perception represents a fundamental underestimation of contemporary CR's scope and purpose. “I would argue the rationale for cardiac rehab is greater than ever, even if a preceding cardiovascular procedure or event is not debilitating,” says Forman.

“We're not just having them walk on a treadmill and reviewing their medications - it's more about opportunities to address cardiometabolic issues, risk factor management and nutritional counseling. It's also addressing the emotional impact of having heart disease, and it's maintaining strength,” he notes.

Emphasizing this point, a recently published randomized trial showed a relative risk reduction of 43% for the composite of cardiovascular death or unplanned hospitalization for cardiovascular

causes within one year with multidomain CR compared to usual care in elderly patients (median age, 80 years) with MI and impaired physical performance (12.6% vs. 20.6%; hazard ratio [HR], 0.57; p=0.01).<sup>3</sup>

Patients in the control group received a single in-person visit at one month after hospital discharge, which included a 30-minute counseling session that was supported by educational materials.

“If you want to provide holistic and effective care, you can't not think of cardiac rehab, because the acute care setting simply does not give you the time to do even half of what's needed,” says Forman.

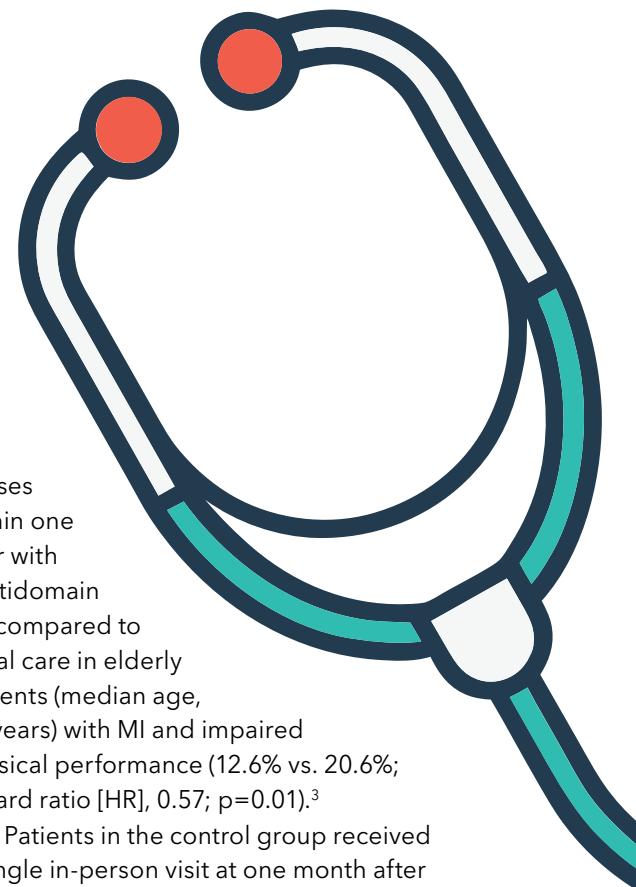
This comprehensive approach is illustrated in the 2024 AHA/AACVPR core components framework for CR programs (**Table**).<sup>4</sup> Standard programs involve 12 weeks of sessions, with most insurance plans covering 36 sessions over this period. Importantly, the model emphasizes how modern CR can be delivered through center-based, virtual or remote methods - or hybrid combinations of these approaches.

Forman suspects that GLP-1 receptor inhibitors may ironically be exacerbating this issue. “Recently, many studies are demonstrating the utility of GLP-1s to reduce cardiac disease. So, many clinicians assume that adding GLP-1s to the regimens of overweight cardiac patients is mostly what's needed.”

“However, if GLP-1s are not paired with CR, I fear we may see an epidemic of muscle loss [and associated frailty] down the line. We know that muscle is crucial for healthy aging and that GLP-1s without exercise can worsen muscle loss,” says Forman, who was the inaugural chair of ACC's Geriatric Cardiology Section.

**Table. Core Components of Cardiac Rehab Program**

	Patient assessment
	30-day individualized treatment plan
	Cardiovascular disease and risk factor management
	Aerobic exercise training
	Strength training
	Physical activity counseling
	Nutritional counseling
	Weight management and body composition
	Psychosocial management



“ The most successful programs are those that implement automated referral protocols, integrated into electronic health records, which eliminate provider-dependent decision-making and eliminate both neglect and bias. ”

Sharonne N. Hayes, MD, FACC

The evolution toward comprehensive and individualized care is particularly relevant as patient demographics shift. "Early on, cardiac rehab primarily served middle-aged White men. Now, we are more aware of social disparities in care and are reaching a broader patient spectrum," notes Forman. "Cardiac rehab is a multicomponent approach that can help us bridge the gaps in care that we see in some groups because it focuses on a broader perspective of management, truly treating the patient holistically."

### Breaking Down Referral Barriers

Multiple systemic barriers contribute to suboptimal CR utilization, including inadequate program capacity, geographic accessibility challenges and insufficient insurance coverage. Yet, the problem often begins with physician assumptions about patient suitability.

"If it's extra work, if it's not in the process or if the clinicians don't understand the benefits of rehab, it very often simply doesn't happen," notes Hayes. She regularly sees patients who were treated elsewhere and hears either that they weren't referred to CR at all after their event or they were told CR wasn't necessary and they should "just do your own thing," she says.

"The most successful programs," Hayes says, are those that implement automated referral protocols, integrated into electronic health records, which eliminate provider-dependent decision-making and eliminate both neglect and bias. Some institutions have implemented "opt-out" rather than "opt-in" models, which can also dramatically improve referral rates.

Financial disincentives compound the challenges of clinician and patient inertia. Unlike procedural interventions, CR generates minimal direct physician revenue, creating perverse incentives that prioritize acute interventions over long-term outcomes. "There's no cardiologist billing for someone to come to cardiac rehab. It's a hospital-based program, so it doesn't really generate as much physician engagement as it might in that respect," Forman explains.

A systematic review that included 19 studies showed that CR was cost-effective compared to no CR, with incremental cost-effectiveness ratios ranging from \$1,065 to \$71,755 per quality-adjusted life-year.<sup>5</sup>

For Forman, HF represents a particularly poignant missed opportunity. "It's ironic to me that referral rates for HF are so low," Forman observes. "There are impediments and comorbidity and complexities of care that have been well described, but HF is a disease that really responds to cardiac rehab."

Historically, patients with HF were assumed to be at risk to exercise and were commonly discouraged from participating in physical activity.<sup>6</sup> Yet, despite evidence of outcome benefits and safety, as well as cost-effectiveness and strong practice guideline recommendations, patients still aren't referred, particularly older patients and women. "Being sedentary because you're fearful of exercising is really the kiss of death spiral down," Forman warns.

Age and impairment also should not be reasons for not referring a patient to CR, he adds. In a just-published Italian trial, 512 elderly patients (median age, 80 years) with impaired physical performance one month after an MI were randomized to either a multidomain rehab intervention (cardiovascular risk factor control, dietary counseling and exercise training) or usual care in a 2:1 ratio.<sup>3</sup>

The intervention group had significantly fewer primary composite events of cardiovascular death or unplanned cardiovascular hospitalization at one year compared to usual care (12.6% vs. 20.6%; HR, 0.57;  $p=0.01$ ), driven primarily by reduced hospitalizations (9.1% vs. 17.6%).

"We have data to show that the sicker the patient, the more they benefit from rehab, so not referring because it seems too little or too late is incorrect," says Hayes.

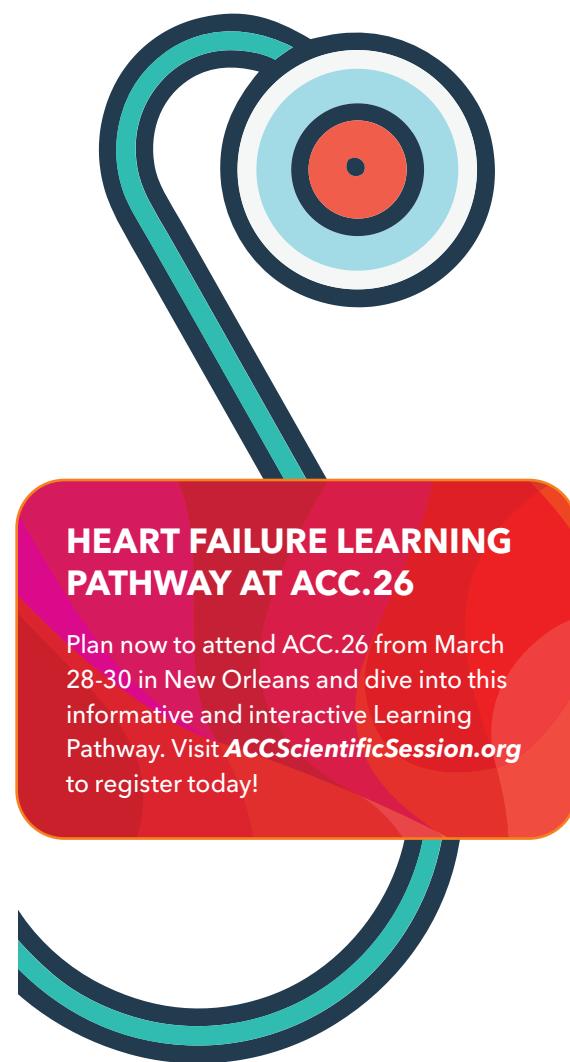
Of course, it's not all on clinicians. Patient-level obstacles are equally significant. Transportation difficulties, work schedule conflicts, costs and family caregiving responsibilities create practical barriers to participation. Cultural factors, including stigma around exercise programs and misconceptions about the purpose of CR, further limit engagement.

Post-discharge support systems have proven crucial for improving participation rates. There have been several studies that have shown that simply having a nurse call within a few days of discharge to ask about medications, symptoms and rehab plans can have a significant impact on completion rates, explains Hayes. This simple intervention addresses the gap between hospital discharge and program enrollment when patients often feel overwhelmed by competing priorities.

### Expanding the Paradigm

Innovative delivery models are addressing traditional barriers to participation. Several trials have looked at the effectiveness and feasibility of home-based CR as an alternative to traditional center-based programs.

In the single-center EXIT-HF noninferiority trial, 120 patients were randomly assigned to either standard CR (24 supervised sessions) or



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home-based CR (four supervised sessions plus 20 home sessions monitored via smartwatch and telephone).<sup>7</sup> Home-based CR was noninferior to center-based CR, with no significant differences in peak oxygen uptake improvement (primary endpoint), 6-minute walk distance, quality of life scores or exercise adherence at 12 weeks.

Another study (iATTEND) randomized 282 patients to hybrid CR (combining one to 12 in-facility sessions with virtual sessions via audiovisual technology) vs. traditional CR.<sup>8</sup> Hybrid delivery did not improve attendance or completion rates, nor did it significantly improve exercise capacity or health status, but the study demonstrated that hybrid CR with virtually supervised exercise is a safe and acceptable alternative to traditional facility-based programs.

Hayes thinks the future of CR lies in creating flexible, individualized programs that meet patients where they are. "I think we're going to see an explosion in remote cardiac rehab, although we still need more data showing it has the same outcomes or at least some good outcomes."

Either way, the evidence supporting CR is unequivocal, she adds. "I talk about it as lifesaving. The data absolutely supports rehab, and the referral and completion rates are poor, so we must do better than this for our patients." ■

References available with the online version of this article at [ACC.org/Cardiology](https://www.acc.org/Cardiology).

# Baylor St. Luke's Medical Center: A Legacy of Continuous Improvement

Setting out on an accreditation journey can seem daunting. Success requires aligning diverse stakeholders, investing in quality tools and education, and prioritizing process improvement.

Over the past decade, Baylor St. Luke's Medical Center in Houston, TX, has partnered with ACC Accreditation Services to earn multiple recognitions: HeartCARE Center designation, Cardiac Cath Lab Accreditation, Electrophysiology Accreditation, Transcatheter Valve Certification, and platinum status in the Chest Pain - MI Registry Performance Achievement Award.

These accolades did not come easy. Their commitment to delivering high-quality patient care and a culture of continuous improvement is what led to their quality achievements. And at this year's ACC Quality Summit, **Seth Stephens, DNP, APRN, ACNP-BC, CPHQ, AACC**, system director for the cardiovascular service line at CommonSpirit Health, and **Karen N. Mullins, MSHS, BGS, RN**, patient safety program manager for Baylor St. Luke's Medical Center, part of CommonSpirit Health, joined Accreditation Review Specialist **Kevin Wehrle, RN, AACC**, to share the impact of their investment in ACC Accreditation.

## Collaborating to Achieve Excellence

When selecting an accreditation program, Stephens and Mullins prioritized alignment with existing registries and quality tools, brand recognition and reputation, and a comprehensive scope of services to support their improvement goals.

“We found that the ACC really focused on and aligned with things that were important to us. A high focus on quality ... performance improvement ... programmatic structure and how we wanted our service line to be governed.”

**Seth Stephens, DNP, APRN, ACNP-BC, CPHQ, AACC**



“We found that the ACC really focused on and aligned with things that were important to us,” said Stephens. “A high focus on quality, high focus on performance improvement, and really thinking about programmatic structure and how we wanted our service line to be governed.”

Wehrle has been their accreditation review specialist since the beginning, meeting regularly to share best practices and encourage innovation within their program. In describing their relationship, Mullins calls Wehrle “a true and lasting partner.”

“Kevin has seen us from very early on when we had very little to no quality infrastructure to now being a very highly functional quality improvement machine,” said Stephens.

This “machine” is powered by collaboration across cardiovascular service lines and extends to the Hospital Quality and Regulatory Committee, Hospital Board and Physician Quality Committee, ensuring improvement efforts are informed by case review and quality data with input from relevant stakeholders at section meetings and medical review boards.

## Improving Outcomes in the Cath Lab

Guiding their quality improvement initiatives in the cath lab, the team targeted two NCDR metrics: Risk Standardized Acute Kidney Injury (AKI) and Risk Standardized Bleeding.

“Focusing on standardized AKI would help us with our patient satisfaction, improve our supply chain, increase our revenue and improve our productivity,” said Mullins. Many of the same benefits were anticipated in reducing bleeding events.

To lower AKI rates in PCI patients, the team implemented a preprocedure hydration protocol, increased intravenous pump availability, improved frailty documentation with abstraction accuracy and a clinician pocket guide, and reviewed AKI cases on a monthly basis with cath lab leadership.

These changes delivered measurable results. Within two months, hydration orders rose by 28%, and from the second quarter of 2022 to the third quarter of 2024, Risk Standardized AKI decreased by nearly 2%.

To reduce bleeding rates, the team continued their efforts to accurately document frailty, reviewed bleeding cases monthly, and prioritized education on closure devices and extracorporeal membrane oxygenation site maintenance. These efforts led to a 0.6% decrease in PCI In-Hospital Risk Standardized Bleeding over the same period.



## RECOGNIZING EXCELLENCE: Q3 2025 ACCREDITED SITES

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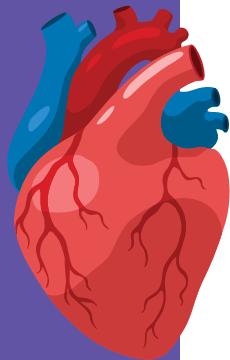


## Common Barriers to Cardiac Program Accreditation

- Staff Resources
- Financial Resources
- Administrative Buy-In
- Physician Buy-In

## Value of the ACC Accreditation Journey

- Staying Survey Ready
- Maintaining Evidence-Based Practices
- Keeping Focus on Patient Outcomes
- Continuous Staff Education on New Procedures and Devices
- Involving a Multidisciplinary Team in QI Data and Planning



“We did make improvement, and we are sustaining those improvements,” said Mullins. “But there’s still more work to do.”

### Quantifying Return on Investment

Stephens emphasized that the true value of accreditation lies in the culture of process improvement it fosters.

Despite decommissioning two of 11 cath labs due to aging equipment, PCI volume increased at their site, thanks to a highly engaged team focused on efficiency.

“We have a cath lab team of frontline leaders and physicians that met every two weeks on efficiency projects where we looked at all of our times...and with looking at each of those pieces in the process, instead of our volume going down, our volume actually went up,” Stephens said.

This is a clear example of how quality improvement can improve financial performance. Both Stephens and Mullins stress that investing time and resources into quality can lead to tangible returns.

Their efforts to reduce AKI and bleeding resulted in an estimated avoidance of 32 cases of AKI, translating to approximately \$384K in cost savings, and 89 bleeding cases, equating to about \$1.6 million saved. Altogether, they estimate \$1.9 million in cost avoidance and more than 100 lives positively impacted throughout this accreditation cycle.

“We have abundantly demonstrated the return on investment that we’ve made both culturally and in dollars and cents,” said Stephens. “And we’re able to articulate that to our C-Suite leaders when they ask every year, ‘Are you sure you need to do that?’” ■

# 4 Tips For Supporting CV Trainees in QI

**A**CC Quality Summit Subcommittee Chair **Olivia N. Gilbert, MD, MSc, FACC**, has helped many of her own residents and fellows foster a passion for quality. She shares four tips on how clinicians, program directors and institutions can help support their trainees in leading through quality improvement (QI) initiatives.

“It’s hard for trainees these days,” says Gilbert. “They’re getting pulled in so many directions and the expectations are getting higher. I think we need to set up a construct for success.”

## 01 Build Infrastructure to Anticipate Trainee Needs

Gilbert emphasizes how a structured environment that removes common barriers for trainees, like lack of funding, mentorship or project ideas, can make a real difference. Institutions can provide resources to help trainees identify strategic QI projects, access funding sources and seek mentors to help bridge these barriers.

## 02 Empower Trainees With Accessible Data and Analytics Tools

Highlighting the shift from manual chart reviews to more efficient data analysis using diagnostic coding and electronic health record-based datasets, Gilbert suggests that training the next generation of clinicians in these new approaches is vital. Joining up-and-coming tools

with high-quality data from established repositories like NCDR will provide the full picture needed to move quality forward.

## 03 Promote and Celebrate Trainee Work

Encouraging trainees to submit their abstracts to meetings on the national stage, like ACC Quality Summit, and platforms for publication, like *JACC: Case Reports*, inspires confidence and reinforces the value of the QI work they are doing. Celebrating their findings both validates their efforts and can help motivate them to continue engaging in the field of quality, according to Gilbert.

## 04 Foster Collaboration With Peers and Mentors

Gilbert highlights the value of peer relationships in sustaining enthusiasm, building community and learning from one another. Mentors also play a pivotal role in connecting resources, sharing differing perspectives, and providing oversight.

**Katherine A. Burns, DO**, one of Gilbert’s fellows at Wake Forest Baptist Medical

Center, submitted her abstract, “Prognostic Performance of CAHP and MIRACLE2 Scores in Out-of-Hospital Cardiac Arrest With STEMI,” to be part of ACC Quality Summit 2025.

Burns and her colleagues found that while both CAHP and MIRACLE2 had “excellent discrimination” for in-hospital mortality, CAHP exhibited “superior independent prognostic value.”

“I hope our project can aid in forming more accurate and meaningful prognoses with regard to outcomes and provide practicing interventionalists with more confidence in making the decision on whether or not to intervene,” Burns says.

This QI work has opened more lines of inquiry. With her interest in the cath lab, Burns hopes to take on additional projects centered around device utilization and electronic medical record workflows with provider alerts.

“I’m thankful Wake Forest has empowered me with the time, tools and resources to start pursuing my ideas on QI in earnest,” she says. ■

## SUBMIT YOUR 2026 NCDR RESEARCH PROPOSALS

Leverage the largest cardiovascular database to explore your clinical questions. **Scan the QR code** to submit a research proposal to use NCDR data by Feb. 6, 2026. Plus, learn more about opportunities for funding and ways to engage in the NCDR Mentorship Program.



# Dive Into the 2026 Medicare Physician Fee Schedule Final Rule

The Centers for Medicare and Medicaid Services (CMS) has released the 2026 Medicare Physician Fee Schedule (PFS) final rule, updating the PFS conversion factor from \$32.3465 to \$33.5675 for qualifying alternative payment model (APM) participants and \$33.4009 for nonqualifying APM participants, increases of 3.77% and 3.26%, respectively. This duality is required by current law. These conversion factors include the 2.5% increase passed in the *One Big Beautiful Bill Act*. The rest of the conversion factor increase stems from policy changes that reduce payment for many services.

The overall reimbursement for cardiovascular services is projected to increase roughly 1% compared with 2025. Individuals and groups will see different impacts depending on patient populations and services offered. Due to other provisions discussed below, facility-based services for cardiology are projected to decline 7% while nonfacility services are projected to increase 5%.

Key proposals relevant to cardiovascular clinicians regarding payment policy are below.

- **Efficiency Adjustment:** The rule finalized an efficiency adjustment of -2.5% to the intra-service times and work relative value units (RVUs) of nearly all non-time-based codes in the PFS, citing efficiencies in performing medical services that accrue over time and are not captured in the normal process of developing the time and work RVUs. The adjustment represents a five-year lookback at the productivity adjustment derived from the Medicare Economic Index. CMS will calculate and apply the efficiency adjustment every three years moving forward. The agency has agreed to exempt any new CPT codes created and initially valued for 2026. This amendment only applies to brand new Category I CPT codes and does not exempt existing codes that were revalued this year.
- **Site of Service Payment Differential:** A significant update to the payment methodology will change the way CMS pays for indirect practice expense (PE). Due to the rise of hospital employment or physician practice integration, CMS reduced the allocation of indirect PE for services performed in the hospital, believing those costs are now born by facilities. For services in the hospital setting, the portion of indirect PE allocated based on work RVUs will be reduced by 50% starting in 2026. This change will produce total RVU reductions of around 10% for facility-based services, such as pacemaker implants, TAVR, PCI, ablation, etc.
- **Left Atrial Appendage Occlusion (LAAO):** Despite efforts to delay revaluation of the LAAO code 33340 due to a restricted and flawed survey, CMS finalized the American Medical Association Relative Value Scale Update Committee (RUC)-recommended value of 10.25, a nearly 27% reduction from the current work RVU of 14.00. The ACC, Heart Rhythm Society, and Society for Cardiovascular Angiography & Interventions are currently resurveying this code for the next RUC meeting.
- **PCI:** The PCI code family was revised at CPT and then resurveyed at the RUC in April 2024 for implementation in 2026. CMS finalized the RUC-recommended values for all 12 codes. Several codes were reduced while others saw an increase in their work RVU. New codes were created for more complex stent cases and revascularization of a chronic total occlusion to allow for more accurate valuation.
- **Lower Extremity Revascularization (LER):** The LER code family was revised at CPT from 16 codes to 46 codes. All RUC-proposed values for the new codes were finalized. CMS may look to hospital outpatient cost data for practice expense in future rules.

- **Remote Physiologic Monitoring:** Several new remote monitoring codes were created and existing codes resurveyed. As these surveys did not reach the minimum response threshold, CMS will maintain the existing code values over the lower RUC recommendations and value the new codes using ratios related to those existing codes. The code family will be resurveyed in January 2028.
- **Baroreflex Activation Therapy (BAT):** Seven of the eight newly created codes for BAT are set at the RUC recommendations. One programming code was moderately reduced via crosswalk to an existing code. CMS adjusted clinical staff to be nurses for device interrogation and programming.
- **Practice Expense:** The rule finalized work and/or PE values for new/ revised codes for LER, BAT, CT coronary plaque assessment and remote physiologic monitoring. More information is available in supporting data tables on values for these and all codes.

Scan the QR code to read more about quality provisions and access other supplemental materials related to the final rule. At the time of print, ACC Advocacy was still waiting on the 2026 Hospital Outpatient Prospective Payment System final rule. ■



## Your ACC Fights For Physician Payment, Opposes Looming Efficiency Adjustment

When CMS released the 2026 Medicare PFS proposed rule earlier this summer, the ACC raised concerns over several policy changes projected to have a significant impact on payment for cardiovascular services. These efforts have continued as many of the proposed policies have now been finalized.

"While the 2026 Physician Fee Schedule includes an increase in Medicare reimbursement passed by Congress, it also relies on new and potentially disruptive payment policies that will significantly impact clinicians and patients during an already uncertain time in health care," said ACC President **Christopher M. Kramer, MD, FACC**.

"In particular, the ACC is concerned that CMS chose to keep the proposed changes to site of service payment differential and efficiency adjustment, despite widespread concerns from the medical community," he said. "These changes overlook the real overhead costs practices face and assume indefinite efficiency gains that could devalue essential services over time. These policies risk undermining practice sustainability across all specialties and limiting access to care for Medicare patients."

Earlier this year, the College joined other medical specialty organizations in a statement addressed to Congress urging long-term reform. Additionally, the ACC recently joined a letter to congressional leadership, requesting they stop implementation of the efficiency adjustment before Jan. 1, 2026. The ACC remains committed to advancing legislation that would include an annual inflationary update to the PFS and raise the budget neutrality threshold to help reduce year-to-year cuts.

Scan the QR code to learn more about ACC's ongoing efforts to establish sustainable Medicare payment practices. ■



# Ambulatory Specialty Model For Heart Failure: Overview and Key Considerations

As part of the Medicare Physician Fee Schedule final rule, the Centers for Medicare and Medicaid Services (CMS) is advancing its most significant and impactful demonstration project for cardiovascular clinicians to date. The Ambulatory Specialty Model (ASM) for heart failure (HF) is a five-year mandatory project aimed at evaluating, scoring and compensating cardiologists for the care of traditional Medicare beneficiaries with HF. The model will be implemented in to-be-selected geographic areas across the country starting Jan. 1, 2027, and will conclude at the end of 2031.

The ASM for HF borrows the existing framework of the Merit-based Incentive Payment System (MIPS) which includes four categories (quality, cost, improvement activities and improving interoperability) to assess participating cardiologists and distribute potential bonuses and penalties from +9% to -9% of their total Part B claims payments. Participant risk levels will increase by 1% each year in performance years 3 through 5.

Once mandatory geographic areas are selected, ASM participation will be limited to physicians with a PECOS-specialty of cardiology who have historically treated at least 20 HF patients per year, identified by the episode-based cost measure methodology. Other specialties likely caring for HF patients and nonphysician practitioners are excluded from the model.

Unlike MIPS, ASM intentionally excludes group or practice-level participation. Each physician will be required to submit the applicable data for each performance category. The performance assessment is based on the following:

<b>Quality Measures</b>	<ul style="list-style-type: none"> <li>MIPS #492: Risk-Standardized Acute Unplanned CV-Related Admission Rates For Patients With HF</li> <li>MIPS #008: HF: Beta-Blocker Therapy For Left Ventricular Systolic Dysfunction (LVSD)</li> <li>MIPS #005: HF: ACE Inhibitor or ARB or ARNI Therapy For LVSD</li> <li>MIPS #236: Controlling High Blood Pressure</li> <li>MIPS #377: Functional Status Assessments For HF</li> </ul>
<b>Cost Measure</b>	<ul style="list-style-type: none"> <li>HF Episode Based Cost Measure, including the following costs, as used in MIPS and the Advancing Care For Heart Disease MVP</li> </ul>
<b>Improvement Activities</b>	<ul style="list-style-type: none"> <li>(IA-1): Connecting to Primary Care and Ensuring Completion of Health-Related Social Needs Screening and Improvement Activity</li> <li>(IA-2): Establishing Communication and Collaboration Expectations With Primary Care Using Collaborative Care Arrangements</li> </ul>
<b>Promoting Interoperability Conditions</b>	<ul style="list-style-type: none"> <li>e-Prescribing</li> <li>Health Information Exchange</li> <li>Provider-to-Patient Exchange</li> <li>Public Health and Clinical Data Exchange</li> </ul>

Each quality and cost measure will be weighted 50% of the final score. The improvement activities and promoting interoperability performance categories are added weights to broaden the distribution of final scores. The maximum scoring adjustment for improvement activities and

promoting interoperability performance categories would be -20 points and -10 points, respectively.

Final scores will determine if participants receive positive, neutral or negative payment adjustments on future claims. Adjustments will be implemented two years after the applicable performance year.

As designed, the ASM excludes the active and important role of advanced practice practitioners, primary care and other specialties caring for HF patients, which the ACC highlighted as a key concern in comments to CMS. Unfortunately, the agency made no significant changes when finalizing the rule.

The ACC will continue to solicit CMS for improvements and is committed to assisting members with this model through educational tools, webinars and Q&A sessions. **Scan the QR code** to access the latest on the ASM for HF. ■



## KEY CONSIDERATIONS FROM ALFONSO H. WALLER, MD, FACC

**Ensure your NPI is current:** ASM will be dependent on the tax-ID number and an individual's National Provider Identifier (NPI) that lists a provider's taxonomy code. Providers may select multiple taxonomy codes but must choose one primary for NPI purposes. Some specialists may be utilizing the "cardiology" taxonomy code, when a more specialized taxonomy code exists for them. ASM will only impact providers that utilize the "cardiology" taxonomy code. Other cardiology taxonomy codes for interventional, electrophysiology, advanced heart failure and transplant, and pediatric are excluded.

**Preparation for mandatory participation:** There is a short lead time for ASM preparation. CMS intends to select geographic regions in early 2026. If you are in a selected geographic region and treat more than 20 HF patients, participation is mandatory.

**Data and measurement readiness:** Cardiologists should work closely with staff involved in quality reporting programs that have financial implications and those that build or implement clinical quality measures within the electronic health record (EHR). Once these measures are built within the EHR, individuals must ensure operational workflows are correctly capturing data needed for these clinical quality measures.

**Financial risk and opportunity:** Excellent performance could lead to positive adjustments, but subpar performance could incur negative adjustments to the individual provider. Investment in organizational infrastructure is warranted to avoid financial penalties and possibly receive a positive adjustment on individual CMS claims.

**Alignment with existing programs:** Although ASM is a new model, it intersects with existing value-based programs like MIPS. Participants should map how ASM overlaps with current reporting and incentives. ■

# Showcasing the Transformative Power of QI

By bringing together quality improvement (QI) professionals across the entire cardiovascular care team, the ACC is working to ensure the highest quality cardiovascular care is delivered to every patient, every time.

This year's ACC Quality Summit, held Oct. 14 to 16 in Denver, was where clinicians could access the resources needed to drive meaningful improvements in patient care, connect with their peers and take actionable knowledge back to their institutions.

**Donald Berwick, MD, MPP**, president emeritus and senior fellow at the Institute for Healthcare Improvement, kicked off the Summit with a keynote address exploring how the definition of quality has expanded over time, highlighting ways today's health care landscape can strengthen quality outcomes, and showcasing opportunities for collective action in improving health care quality. **Scan the QR code** to learn more about his perspective on reimagining quality.



Other sessions tackled how to derive meaning from QI metrics, the role of executive management in elevating outcomes and ways artificial intelligence is shaping cardiovascular quality.

In addition to sharing new offerings and enhancements from NCDR and ACC Accreditation Services, the three-day event provided a forum where clinicians could learn from quality initiatives being pioneered at other facilities.

More than 200 ePosters were on display, showcasing the breadth of quality work being done throughout the U.S. and abroad. **Scan the QR code** to read about key findings from top-scoring abstracts. ■



## PRESENTED AT THE SUMMIT, PUBLISHED IN THE JOURNAL

More than 30 abstracts presented at ACC Quality Summit were accepted by *JACC: Case Reports* for inclusion in a QI special issue released Nov. 12.

The featured investigators are taking their scientific contributions to quality beyond the Summit, earning recognition through publication! **Scan the QR code** to explore the issue and learn how you can submit your own clinical care delivery cases to the journal. ■





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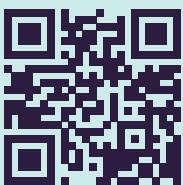
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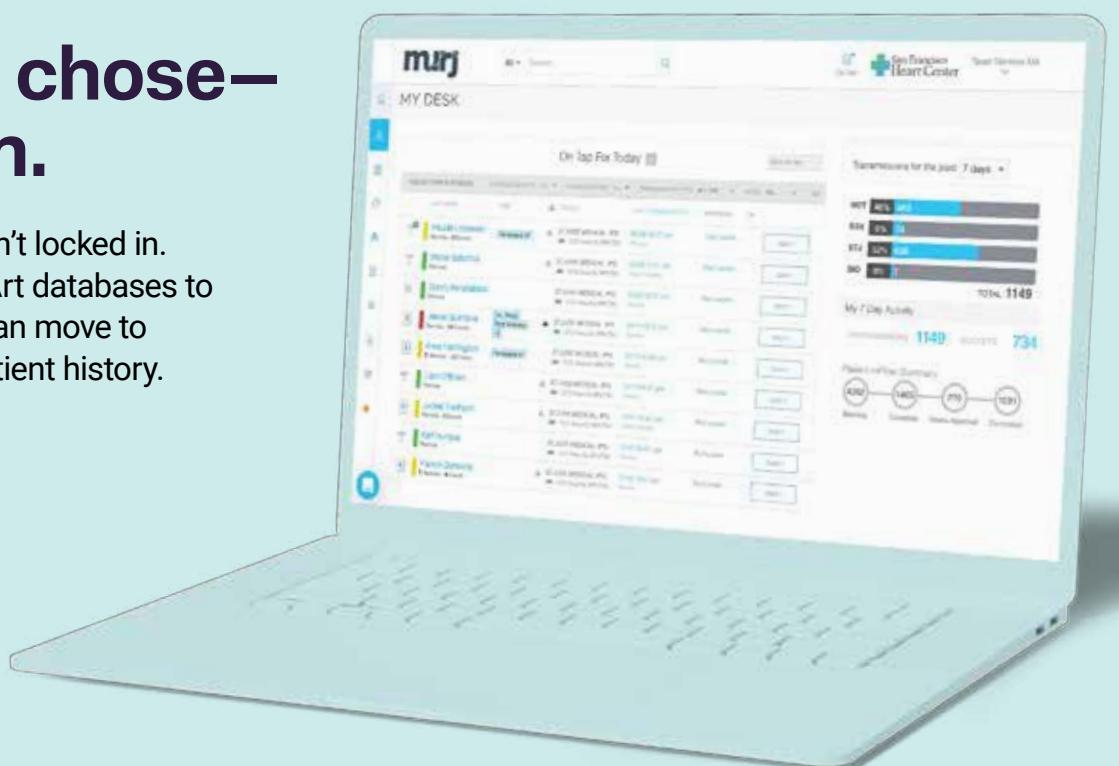
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