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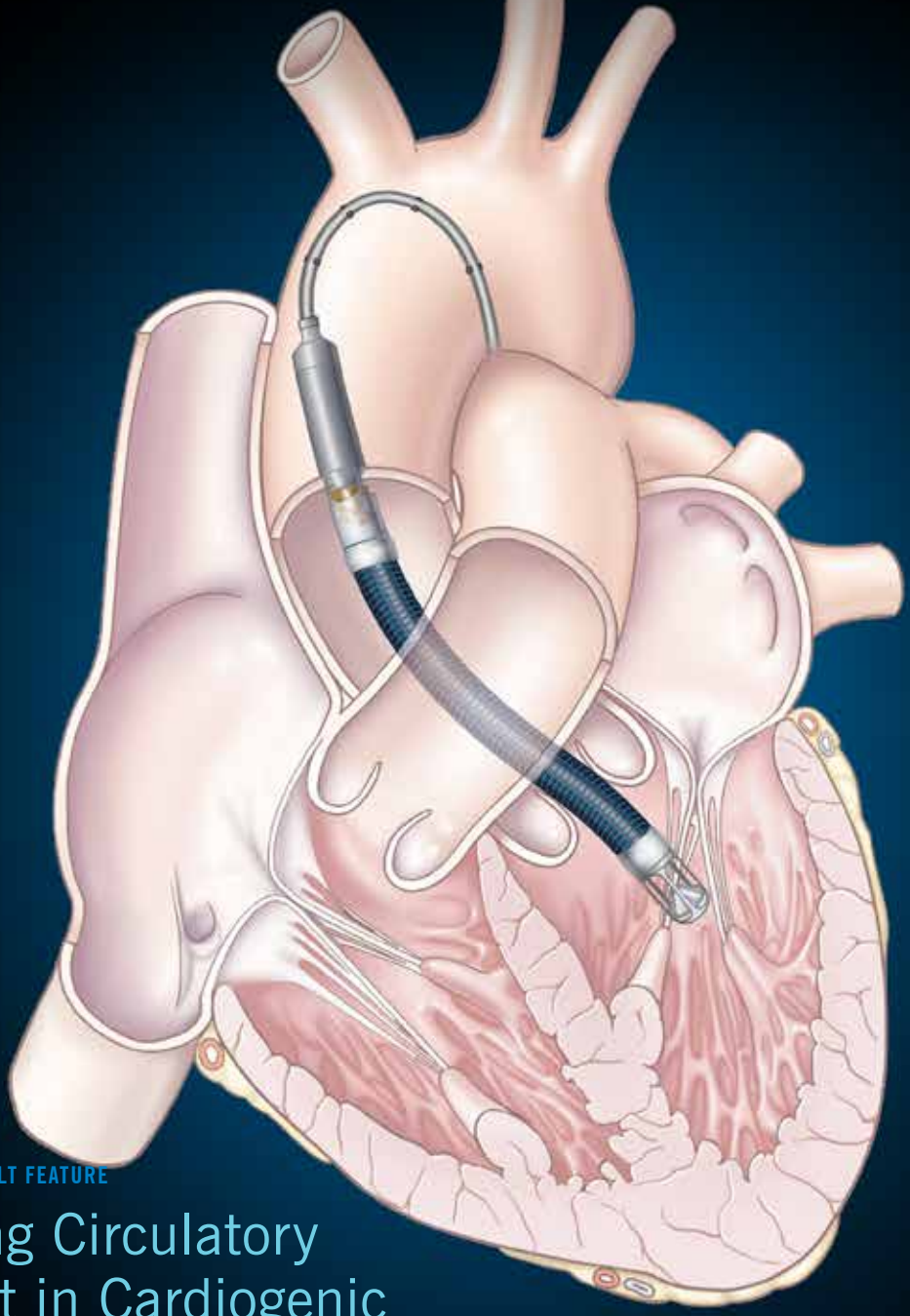

› CARDIAC CONSULT FEATURE

Weaning Circulatory Support in Cardiogenic Shock – p. 4

Dear Colleagues,

At Cleveland Clinic, multispecialty and multidisciplinary collaboration is so central to the care of patients with complex disease that we explicitly embrace what we call a "team of teams" approach.

That approach is exemplified in the cover story of this issue of *Cardiac Consult*. The article profiles how our cardiogenic shock team addresses a long-standing dearth of guidance around a key clinical challenge: when and how to wean patients from temporary mechanical circulatory support for refractory cardiogenic shock.

As the story makes clear, weaning is not a single event but rather a constant reevaluation of a patient's readiness to move to the next, most appropriate support therapy. That vigilant reevaluation is a team-based exercise in which diverse clinicians huddle on a regular basis, all of them drawing on their respective expertise to enable quick pivoting to a new strategy whenever indicated. It is team-of-teams culture in action.

Our Heart, Vascular & Thoracic Institute brings this culture to bear for our patients at every turn, from deciding on open or endovascular repair for aneurysms of the descending aorta (see p. 8) to pooling the expertise of our cardio-oncology specialists with that of Cleveland Clinic's artificial intelligence experts to enhance cardiac risk stratification in cancer patients (see p. 14).

Please know that if you enlist our assistance in the management of one of your most challenging cases, we will apply this same team-of-teams approach to your patient's care. It is the Cleveland Clinic way.

Respectfully,

Lars G. Svensson, MD, PhD

CHAIR | Sydell and Arnold Miller Family Heart, Vascular & Thoracic Institute

Cardiac Consult is produced by Cleveland Clinic's Sydell and Arnold Miller Family Heart, Vascular & Thoracic Institute.

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Cleveland Clinic was named a top U.S. hospital in *U.S. News & World Report*'s "Best Hospitals" rankings for 2021-22, as well as the No. 1 hospital in cardiology and heart surgery for the 27th consecutive year.

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image OF THE ISSUE

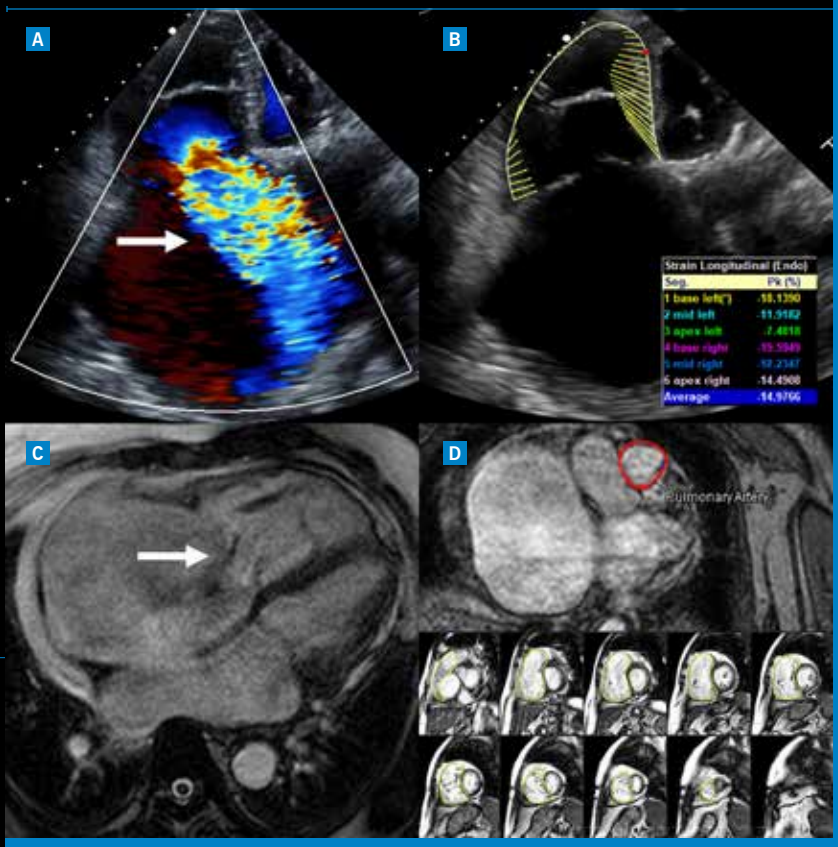
Isolated tricuspid regurgitation is a high-risk condition and increasingly seen, but its management is controversial. A new Cleveland Clinic study has demonstrated that adding cardiac magnetic resonance imaging (CMR) to transthoracic echocardiography (TTE) and clinical history assessment can help identify which patients have severe valve regurgitation and are most likely to have a poor outcome, with the aim of potentially guiding management decisions.

The retrospective study (*Circ Cardiovasc Imaging*. Epub Sept. 15, 2021) assessed predictors of mortality among 262 consecutive patients with at least moderate-to-severe isolated tricuspid regurgitation who underwent CMR (in addition to TTE) at Cleveland Clinic. The three most important imaging and clinical predictors were:

- CMR-derived tricuspid regurgitation fraction or volume
- TTE-derived right ventricular free wall longitudinal strain
- Right heart failure, as determined by clinical history or physical examination assessment

"Use of CMR in isolated tricuspid regurgitation has grown in recent years at Cleveland Clinic, and this study for the first time defines the thresholds for severe tricuspid regurgitation and confirms prognostic utility," says the study's first author, Tom Kai Ming Wang, MBChB, MD. "These findings suggest that combining this multimodality imaging approach with clinical evaluation is a compelling strategy for assessing risk and timing management in this challenging patient population." ■

For more on the study, see ccf.org/isolatedtr.



Multimodality imaging evaluation of isolated tricuspid regurgitation. (A) Color Doppler of severe tricuspid regurgitation (arrow) in apical right ventricle view by transthoracic echocardiography (TTE). (B) Right ventricular longitudinal strain evaluation by TTE using velocity-vector imaging software (yellow trace). (C) Cine sequence four-chamber view showing severe tricuspid regurgitation (arrow) by cardiac magnetic resonance imaging (CMR). (D) Quantification of tricuspid regurgitation volume (TRRV) and fraction (TRRF) by CMR involving calculation of pulmonary artery forward flow (PA flow; top, red trace) with phase contrast sequence and calculation of right ventricular stroke volume (RVSV; bottom, yellow traces) with cine short-axis stack sequence. TRRV = RVSV – PA flow; TRRF (%) = TRRV/RVSV.

Weaning Circulatory Support in Cardiogenic Shock: A Team-Based Art Form

Weaning patients from temporary mechanical circulatory support for cardiogenic shock is fundamentally a team exercise. Here clinicians from the multidisciplinary cardiogenic shock team hold a hybrid virtual/in-person huddle with remote team members to discuss weaning strategies for patients.

Circulatory Support in Cardiogenic Shock: Weaning Is Just as Important as Initiation

As multidisciplinary cardiogenic shock teams have proliferated, there has been no shortage of literature guidance on when and how to initiate temporary mechanical circulatory support (TMCS) in patients with or at risk for refractory cardiogenic shock. In contrast, however, standardized guidance on when and how to wean these patients from TMCS devices has been minimal to nonexistent.

Now, a diverse team of Cleveland Clinic subspecialists has filled that void with a singular paper, "A Pragmatic Approach to Weaning Temporary Mechanical Circulatory Support," that reviews the literature on this question, shares results from a survey of expert opinion, and presents Cleveland Clinic's approach and algorithms for weaning patients from this support. Their work was published as a State-of-the-Art Review in *JACC: Heart Failure* (2021;9[9]:664-673).

"There is considerable heterogeneity in practice around when and why to wean, even within institutions," says the paper's senior author, Jerry Estep, MD, Medical Director of Cleveland Clinic's Kaufman Center for Heart Failure Treatment and Recovery. "We undertook this paper with a threefold aim: to define and outline key concepts in decision-making around device weaning, to summarize the published literature and capture current expert opinion, and to share Cleveland Clinic's approach in this realm."

Stakes are high

The impetus was an unmet need for guidance in developing exit strategies for a high-stakes clinical scenario. TMCS is used to restore adequate tissue perfusion to stabilize patients with cardiogenic shock so that the advanced heart disease underlying the shock can be treated. Sometimes the end result is heart recovery following interventions such as stenting or valve replacement. Often, however, disease is sufficiently advanced to require heart transplantation or placement of a durable left ventricular assist device (LVAD).

"Each of these exit strategies has a narrow window of opportunity," observes heart failure cardiologist Ziad Taimeh, MD, a co-author of the new paper and member of Cleveland Clinic's cardiogenic shock team. "Weaning the mechanical support too early can result in destabilization, while weaning too late can lead to device complications that preclude safe transition to a subsequent exit strategy. Structured weaning strategies need to be in place to enable accurate assessment of that window of opportunity on a daily basis."

He notes that demonstrating TMCS dependency with attempted device wean trials is included for rejustification of heart transplant listing status in the 2018 revision of the United Network for Organ Sharing policy for adult heart allocation.

"The decision to place temporary mechanical circulatory devices in hemodynamically unstable patients should not be instinctive but guided by clear, targeted support and unloading strategies that pay attention to the underlying pathological substrate — and the possible exit strategy," adds co-author Venu Menon, MD, Director of Cleveland Clinic's Cardiac Intensive Care Unit. "Having a systematic and thoughtful weaning strategy to enable the clinician to gauge the presence or likelihood of ventricular recovery is a central principle of adopting this approach."

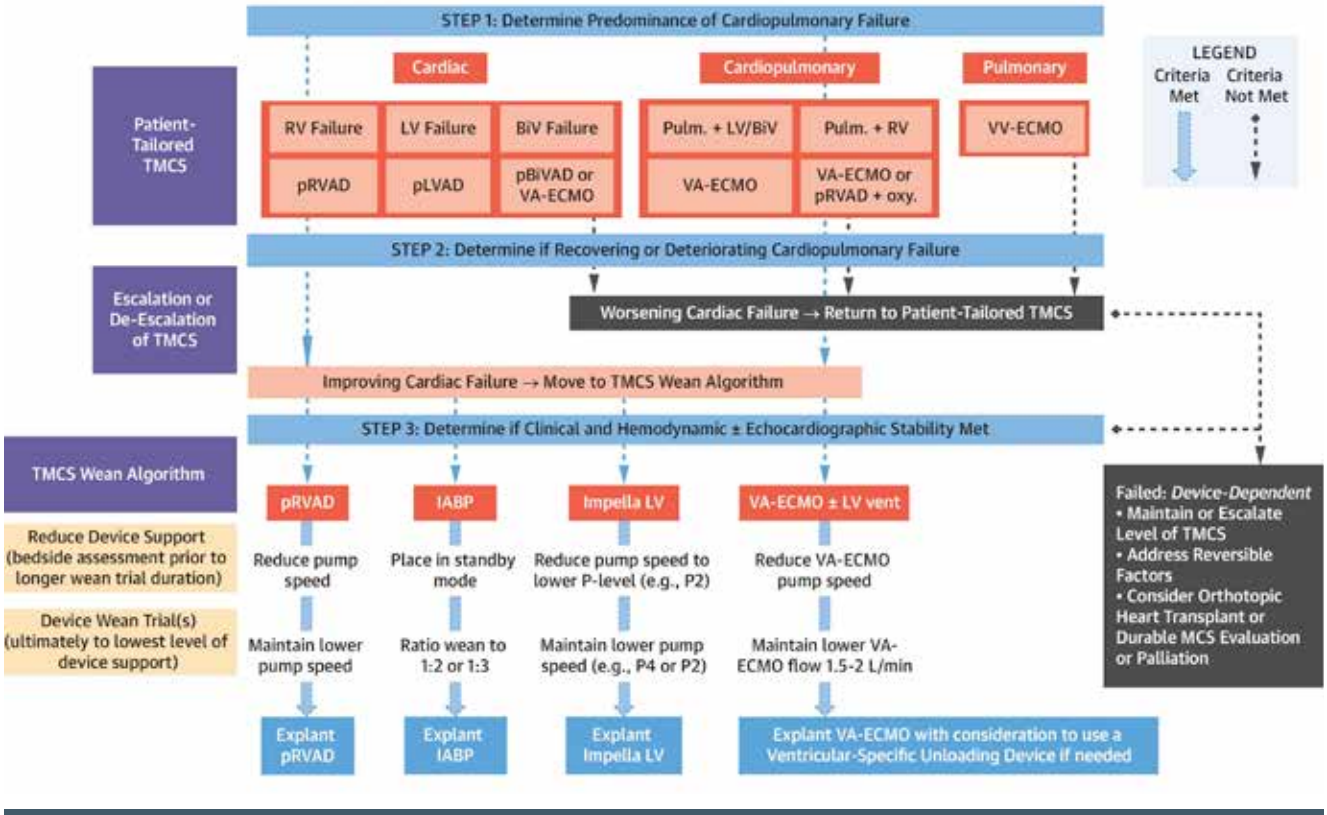
Three windows into structuring weaning strategies

The new paper provides three windows into developing structured weaning strategies:

- The literature review portion succinctly synthesizes results from 50 identified studies that describe TMCS weaning or explant strategies. Findings are presented by device, including intra-aortic balloon pumps, microaxial flow Impella® devices, TandemHeart® systems and venoarterial extracorporeal membrane oxygenation (VA-ECMO).
- The expert opinion portion summarizes areas of agreement and divergence among 34 centers that responded to a survey of members of the Cardiogenic Shock and International Society of Heart and Lung Transplantation MCS Working Groups.
- The rest of the paper shares essentials of Cleveland Clinic's approach to TMCS use, weaning and explant, including a device-tailoring algorithm for TMCS (Figure). "Our approach to cardiogenic shock involves individualized patient assessment and treatment that prioritizes early TMCS device tailoring for an upper-body ventricular-specific unloading strategy, liberation from mechanical ventilation and prevention of physical deconditioning through ambulation," notes cardiothoracic surgeon Aaron Weiss, MD, a co-author of the paper and member of Cleveland Clinic's cardiogenic shock team.

continued next page

Device-Tailoring Algorithm for Temporary Mechanical Circulatory Support



Randhawa VK, et al. *JACC: Heart Failure.* 2021;9(9):664-673

Figure. Cleveland Clinic's device-tailoring algorithm for TMCS in patients with cardiogenic shock. Reprinted from *JACC: Heart Failure* (2021;9[9]:664-673), ©2021 The Authors. BiV = biventricular; IABP = intra-aortic balloon pump; LV/RV = left/right ventricular; oxy. = oxygenator; Pulm. = pulmonary; pRVAD/pLVAD = percutaneous right/left ventricular assist device; VA/VV-ECMO = venoarterial/venovenous extracorporeal membrane oxygenation

Principal takeaways

The authors of the paper identify a number of key takeaways, outlined below, arising from their review of evidence and opinion as well as from the Cleveland Clinic cardiogenic shock team's experience in recent years.

Think in terms of "readiness to wean." "One of our objectives was to raise awareness of the concept of 'readiness to wean,'" says Dr. Estep. "There are risks related to ongoing support if patients stay on a TMCS device longer than needed. It's important for cardiogenic shock teams to have concrete criteria defined in advance for when to start attempting to wean a patient from a given device. And these criteria should be comprehensive — reflecting clinical features, hemodynamic responses and metabolic parameters — rather than being based on just a few measures." The paper shares guidance for defining such criteria, as well as recommendations on how to wean from various devices.

Adopt a truly tailored approach. No one TMCS device fits every patient or every stage within the continuum of cardiogenic shock. Similarly, weaning strategies differ for different devices and different stages of a patient's disease course. "It's important for the cardiogenic shock team to understand where they intend to go with a device, because with each device you have multiple avenues and exit strategies," observes co-author Edward Soltesz, MD, MPH, Surgical Director of the Kaufman Center for Heart Failure Treatment and Recovery.

He cites the example of a patient who presents in hemometabolic collapse and requires urgent cannulation for VA-ECMO. "Their metabolic status may improve very rapidly," he says, "at which point what they need is hemodynamic ventricular-specific support, which means they should be weaned and decannulated from VA-ECMO and transitioned to the appropriate subsequent support strategy."

> "Weaning the mechanical support too early can result in destabilization, while weaning too late can lead to device complications that preclude safe transition to a subsequent exit strategy." — Ziad Taimeh, MD

Whereas some programs may be perceived as "an ECMO program" or "an Impella program," the goal should be to offer all TMCS devices in what Cleveland Clinic calls a tailored approach to cardiogenic shock. "We have all the devices available and use them to achieve patient stability in the least invasive way and accomplish our goal for the patient from a ventricular support standpoint," Dr. Soltesz explains. "When needed, it's appropriate for a smaller center to reach out to a tertiary or quaternary center on a challenging case rather than deeming a patient not weanable."

Approach weaning as a team exercise. As Cleveland Clinic's cardiogenic shock team has evolved, it has become broader and more collaborative, particularly in decision-making around device weaning. "To properly manage these complex cases, it is imperative to involve a multidisciplinary team of experts, including cardiologists and cardiac surgeons specializing in heart failure and transplantation, critical care cardiologists, interventional cardiologists, perfusionists, and nurses and advanced practice providers specializing in these areas," says Dr. Taimeh.

At Cleveland Clinic, these clinicians gather at a virtual huddle every afternoon to make decisions about — and adjustments to — device strategies for their cardiogenic shock patients. At these huddles the multidisciplinary team reviews key clinical, hemodynamic and metabolic features — blood pressure and heart rate, cardiac performance as assessed by right heart catheterization, lactate levels, end-organ function, medication requirements and more — to assess patient stability in the context of Cleveland Clinic's algorithms for readiness to wean. "The multidisciplinary expertise on hand allows us to quickly pivot to new strategies if needed," Dr. Estep notes. "The establishment of the team and the regularity of the huddles ensure that we all speak the same language and are following shared criteria."

Recognize that weaning is not a single event. "Weaning is a constant reevaluation of a patient's readiness to move to the next, most appropriate support therapy," Dr. Soltesz says. Cleveland Clinic's cardiogenic shock team continuously monitors patients over defined periods to assess their likelihood of remaining stable on lower levels of support, often with rapid or slow device wean trials. "Sometimes the assessment will result in device removal," Dr. Soltesz continues. "Sometimes it will involve therapy de-escalation or even escalation. Other times it will lead to transitioning to a different temporary support device or pivoting to transplant or a durable LVAD. Weaning is a process, not just a single event."

Next up: Laying groundwork for prospective data insights

The authors note that the historical dearth of guidance on TMCS weaning stems in part from the challenges of researching this issue. Sample sizes are small, patient phenotypes vary widely and granular data are needed across a broad set of patient measures.

> "Weaning is a constant reevaluation of a patient's readiness to move to the next, most appropriate support therapy.... [It] is a process, not just a single event."
>
> — Edward Soltesz, MD, MPH

To overcome these challenges, Cleveland Clinic is leveraging its electronic medical record to develop a prospective cardiogenic shock database to capture discrete data before, during and after device therapy to analyze short- and long-term patient outcomes. "It will encompass the various device strategies and help us continually improve our processes as well as share best practices with other cardiogenic shock teams," says Dr. Weiss. ■

Contact Dr. Estep at 216.444.7646, Dr. Taimeh at 216.444.9636, Dr. Menon at 216.445.5390, Dr. Weiss at 216.636.2204 and Dr. Soltesz at 216.444.5680.

Open or Endovascular Repair for Aneurysms of the Descending Aorta?

Intermediate outcomes favor an open approach in propensity-matched analysis

Open repair of descending thoracic and thoracoabdominal aortic aneurysms achieved acceptable near-term outcomes and superior intermediate-term outcomes relative to endovascular repair, finds a propensity-matched analysis from Cleveland Clinic published online in the *Annals of Thoracic Surgery* earlier this year.

"Endovascular repair is increasingly used in this setting, extending beyond patients at high risk from open surgery to those at moderate and low risk," says the study's lead author, Michael Tong, MD, MBA, of Cleveland Clinic's Department of Thoracic and Cardiovascular Surgery. "This trend is fueled by patients' preference for the less-invasive nature of endovascular repair despite open repair being the gold standard for these aneurysms. Yet while early results with endovascular repair have been good, later outcomes have not been well described."

Comparing 10 years of experience with both approaches

To help fill the data void, he and colleagues analyzed all 1,053 patients who underwent repair of descending thoracic or thoracoabdominal (Crawford extent I, II or III) aortic aneurysms at Cleveland Clinic from January 2000 to January 2010. Of these, 457 (43.4%) had open repair and 596 (56.6%) had endovascular repair.

To best match patient characteristics for comparing clinical outcomes out to 10 years, the researchers performed propensity-score matching. The resulting 278 well-matched pairs represented 61% of possible pairs.

Short-term outcomes favor endovascular repair

Comparison of the matched cohorts revealed statistically similar in-hospital outcomes with regard to the following:

- Mortality (8.3% with open repair vs. 7.6% with endovascular repair)
- Spinal cord ischemia (4.0% vs. 5.1%, respectively)
- Permanent paralysis or paraplegia (3.6% vs. 2.2%, respectively)
- Stroke (5.4% vs. 3.3%, respectively)

In contrast, patients receiving open repair had higher rates of acute kidney failure (8.6% vs. 3.3%; $P = 0.008$) and prolonged ventilation (46.0% vs. 6.3%; $P < 0.0001$) as well as a longer median ICU stay (5 vs. 3 days; $P < 0.0001$) and a longer median postoperative hospital stay (11 vs. 6 days; $P < 0.0001$).

Intermediate-term outcomes favor open repair

Comparison of the matched cohorts revealed significantly higher rates of 10-year survival with open repair versus endovascular repair ($P < 0.0001$). Survival rates were as follows:

- Open repair: 89% at 6 months, 88% at 1 year, 74% at 5 years, 52% at 10 years
- Endovascular repair: 87% at 6 months, 82% at 1 year, 55% at 5 years, 33% at 10 years

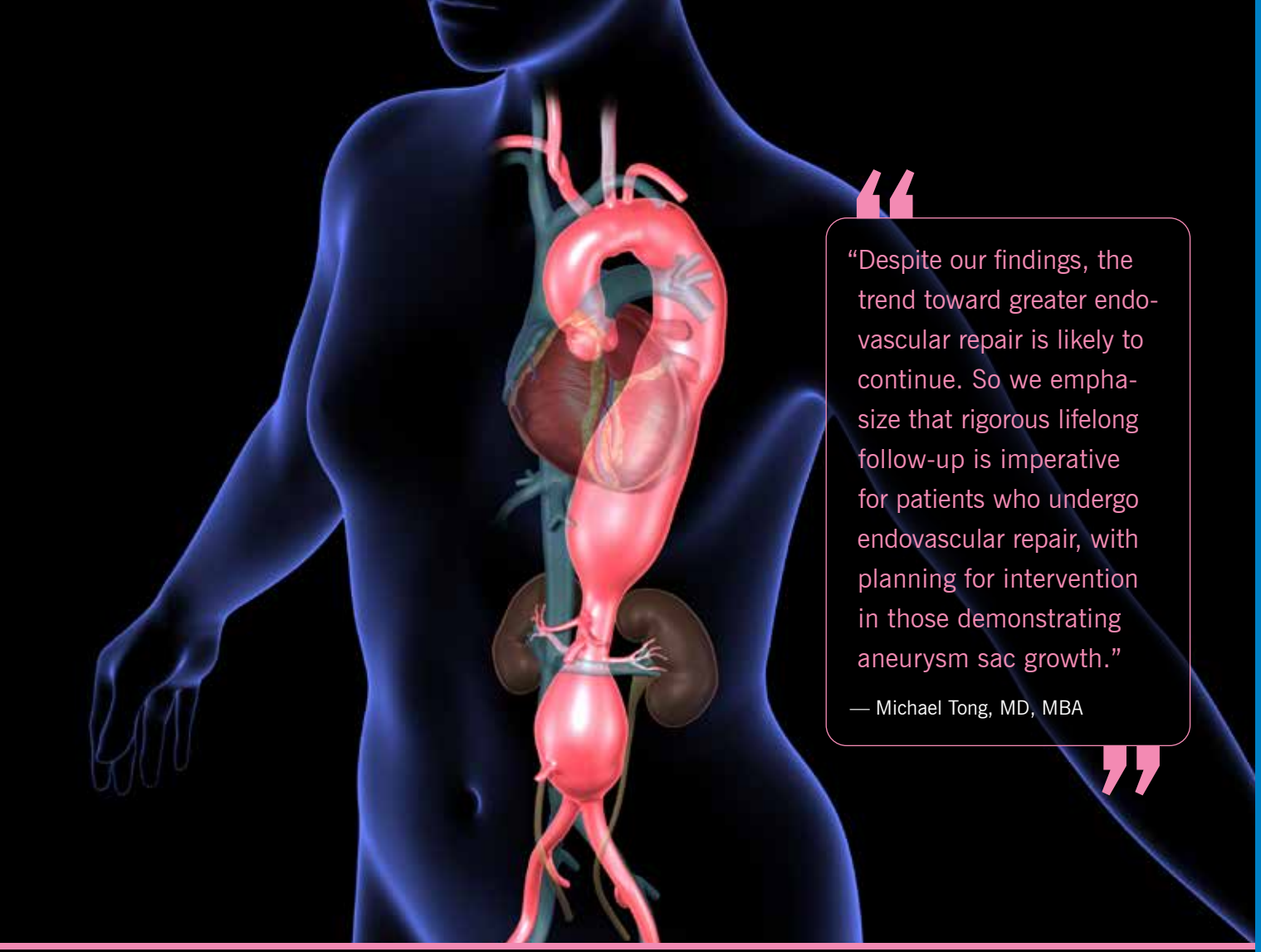
Freedom from aortic reintervention was higher in the open repair group than in the endovascular repair group at 1 year (99% vs. 96%, respectively), 5 years (98% vs. 88%) and 10 years (96% vs. 79%) ($P < 0.0001$).

Within the endovascular repair cohort, average aorta size declined in the first two postoperative years and then slowly increased but failed to recover to normal range.

Reasons for the mortality divergence

"After the early hazard phase, we found a survival advantage with open repair compared to endovascular repair," Dr. Tong says. He and his co-investigators write that the reasons for the divergence in mortality over time may be associated with patient selection and device failure.

"These data are consistent with open infrarenal aortic repair outcomes, in which early benefits are lost over the long term due to the need for late reinterventions and progression of aortic disease," says study co-author Sean Lyden, MD, Chair of Vascular Surgery at Cleveland Clinic. "We also need to remember that patients undergoing endovascular repair of thoracoabdominal aneurysms at our institution were treated in the context of a physician-sponsored IDE study in which patients were deemed high risk for open repair by our surgeons. This led to a large number being dropped from analysis after propensity matching, whereas use of approved thoracic stent grafts allowed landing in suboptimal aortic zones and achievement of early success."



> "Despite our findings, the trend toward greater endovascular repair is likely to continue. So we emphasize that rigorous lifelong follow-up is imperative for patients who undergo endovascular repair, with planning for intervention in those demonstrating aneurysm sac growth."
>
> — Michael Tong, MD, MBA

He adds that endovascular repair, when done optimally, should put more residual aorta at risk since the device has to land 2 cm above and below the aneurysmal area, in contrast to open surgery, where a suture line can be made right at the junction of the diseased and nondiseased areas.

Lessons on spinal cord protection and landing zones

The investigators note that the experience reflected in this study underscores two key lessons. One is the importance of meticulous spinal cord protection during open repair. "We were gratified to find no difference in paraplegia or paralysis in our series, in contrast to prior reports," says Dr. Tong. "This is a testament to advances in spinal cord protection during open aorta surgery in recent decades. All our patients who undergo procedures on the thoracoabdominal aorta receive cerebrospinal fluid drainage."

Another lesson is the priority to be given to landing zones. "Patients with devices landing in the arch with coverage of branch vessels undergo arch vessel revascularization," Dr. Lyden says. "And our cardiac teams increasingly perform elephant trunk and frozen elephant trunk procedures to augment the landing zones of descending aortic stent-grafts."

Takeaways in view of endovascular trends

In their study report, the authors note that endovascular repairs in this patient population increased by 60% from 1998 to 2007 while open repair volume growth was flat. "Despite our findings, the trend toward greater endovascular repair is likely to continue," Dr. Tong observes. "So we emphasize that rigorous lifelong follow-up is imperative for patients who undergo endovascular repair, with planning for intervention in those demonstrating aneurysm sac growth. And our findings argue for open surgery in patients with poor landing zones and in young patients with low surgical risk and long life expectancy." ■

Contact Dr. Tong at 216.445.0807 and Dr. Lyden at 216.444.3581.

Tech-Assisted Approach Pinpoints Candidates for Non-Rx Statin Therapy

Web-based self-selection tool aims to achieve long-sought nonprescription statin access

Only about half of individuals who are eligible for statin therapy actually receive statin treatment, according to recent registry data. To take fuller advantage of statins' benefits for primary and secondary cardiovascular prevention, some public health advocates have proposed making low-dose statin therapy available without a prescription. However, five separate efforts to obtain U.S. regulatory approval for over-the-counter statins have failed to date. The main reason: an inability to show that consumers could appropriately self-select for treatment.

Now a new study has shown that using a novel approach — *technology-assisted self-selection* — to qualify consumers for nonprescription statin treatment was successful in ensuring that a high percentage of ineligible consumers were denied access and only those at an appropriate level of cardiovascular risk were deemed eligible. The study used a web application to evaluate whether U.S. consumers can appropriately self-select for treatment with rosuvastatin 5 mg once daily by measuring agreement between consumer assessment and clinician assessment of treatment eligibility. Its results were published in the *Journal of the American College of Cardiology* (2021;78[11]:1114-1123).

"By demonstrating a high level of concordance between consumer assessment and clinician assessment of eligibility for statin treatment, our study demonstrates this new technology-assisted approach can overcome traditional barriers and may be a good model for achieving the goal of safe nonprescription access to statins for appropriate individuals," says lead author Steven Nissen, MD, Chief Academic Officer of Cleveland Clinic's Heart, Vascular & Thoracic Institute.

An intricate study design

The web application used in the study was programmed to reflect the 2018 American College of Cardiology/American Heart Association (ACC/AHA) cholesterol treatment guidelines for moderate-intensity statin therapy, as well as the proposed warnings and precautions for nonprescription rosuvastatin ("drug facts" label), using the ACC/AHA risk calculator pooled cohort equations for calculating cardiovascular risk.

The study's 500 participants were recruited from the general population through advertising. Enrollees had to be at least 20 years old and able to speak and read English. Enrollment was regulated to preclude excessive numbers of young and old individuals who would be deemed statin-ineligible solely due to age. Additionally, the design required at least 16% of enrollees to have limited literacy to reflect real-world literacy levels.

Study participants accessed the web-based application at home or a location of their choice, responding to questions about their medical history, medication use, cholesterol levels (total, LDL, HDL), triglycerides, blood pressure and, if needed, waist circumference, high-sensitivity C-reactive protein level and coronary calcium score.

Based on their responses, participants were assigned one of three self-selection outcomes:

- "OK to use rosuvastatin 5 mg/day" (eligible)
- "Not right for you" (ineligible)
- "Ask a doctor" (further assessment needed)

Participants were considered ineligible for nonprescription therapy if their cardiovascular risk score was less than 5% or greater than 20%, if they had a risk between 5% and 7.5% without a risk-enhancing factor, or if they had a contraindication to rosuvastatin.

After completing the online self-selection, participants were directed to a research site for a scheduled visit and told to bring verification of their laboratory values and blood pressure as reported through the web application. If verification wasn't available, these measures were taken on-site. The information collected at the site visit was sent to a telemedicine clinician, who conducted an independent medical evaluation and used this information, together with the verified lab and blood pressure data, to complete a technology-assisted assessment via the same web application used by the participant. Clinicians were blinded to participants' web entries, and both partici-

pants and clinicians were blinded to the self-selection outcome that participants were assigned by the web application.

The primary endpoint was the proportion of participants whose self-selection outcome for nonprescription rosuvastatin matched that of the clinician's technology-assisted assessment.

Results show robust concordance

Among 1,563 volunteers assessed for study inclusion, 1,063 were sent a link to the web-based application. Of these, 563 did not schedule an on-site visit, leaving a final cohort of 500 with both a self-selection assessment and a clinician assessment. These patients had a mean age of 59.2 years and were 62.2% female and predominantly White (61.0%) or Black (33.2%). Forty-five percent had graduated from college or a technical school. The 563 participants who did not schedule on-site visits were demographically similar to this cohort.

Key results were as follows:

- 481 of the 500 participants had agreement between their self-selection outcome and clinician assessment, for a concordance rate of 96.2% (95% CI, 94.1%-97.7%).
- 23 of the 500 participants (4.6%) were deemed eligible for nonprescription statin therapy, and 458 (91.6%) were deemed ineligible.
- Discordant assessments were due to incorrect participant self-selection ("OK to use") in three cases, incorrect declines ("not right for you") in 14 cases and an inappropriate "ask a doctor" outcome in two cases.
- Overall, 81.0% of participants (95% CI, 77.3%-84.3%) answered all questions in concordance with clinicians.

Differences from prior nonprescription efforts

"These findings show that using a technology-assisted self-selection tool for nonprescription statin therapy resulted in consumer self-selection that substantially agreed with clinician selection," Dr. Nissen observes.

Additionally, a similar rate of concordant outcomes — 96.4% — was observed within the subgroup of participants with limited literacy. "This is important since consumers with limited literacy may have reduced access to the healthcare system and thus may benefit more from nonprescription access to statin therapy," Dr. Nissen says.

He notes that it was expected that a large majority of study participants (91.6%) would be deemed ineligible for nonprescription statin therapy because the study was designed to enroll a broad sampling of the general population. Such a design is necessary because a failure to prevent treatment access for ineligible consumers was a key shortcoming of earlier attempts to provide nonprescription access to statins.

Dr. Nissen says this study's small number of incorrect self-selections for therapy — just three cases out of 500 — is impressive in light of those prior efforts. "Incorrect self-selection can raise safety concerns by permitting access to medication among consumers who are not likely to benefit or who may be at risk for adverse effects," he says.

Prior over-the-counter statin programs' lack of success can be explained by two key factors, the study authors write:

- Sole use of the drug facts label to guide consumers on self-selection decisions
- The choice of statin for nonprescription therapy

In contrast, they note, the web application in this technology-assisted approach supplemented the drug facts label with cholesterol treatment guidelines and with the ACC/AHA calculator for determining cardiovascular risk. Additionally, rosuvastatin 5 mg/day was chosen because it has greater efficacy in LDL cholesterol reduction than other statin entry doses while also demonstrating "a safety profile appropriate for use in a nonprescription setting," they write.

Next steps

If the study's web-based application receives FDA approval, its proposed development program would allow consumers who are deemed eligible after completing the web application to make an online purchase of rosuvastatin 5 mg without a prescription. The medication would be shipped directly to the consumer and would not be available for over-the-counter purchase in pharmacies or stores. Renewal reminders would be emailed to purchasers as their medication supply dwindled, directing them back to the web application for a brief health reassessment to confirm their continued eligibility.

The study authors note that future investigations are needed to enroll consumers with a high likelihood of eligibility for nonprescription rosuvastatin in order to learn whether this approach can improve appropriate selection of therapy candidates and to evaluate their adherence to treatment and long-term clinical outcomes. ■

The study was funded by AstraZeneca Pharmaceuticals.

Contact Dr. Nissen at 216.445.6852.

FOLLOW THESE 10 COMMANDMENTS

FOR

Successful Multiarterial Grafting in CABG

Cleveland Clinic surgeons outline best practices for optimal outcomes

The use of at least two arterial grafts improves outcomes of coronary artery bypass grafting (CABG) for multivessel disease, yet more than 93% of patients undergoing CABG in the United States receive only a single graft and over 80% of conduits are saphenous vein grafts. That's despite recent Society of Thoracic Surgeons guidelines urging use of additional internal thoracic artery (ITA) and/or radial artery grafts as a supplement to the ITA-to-LAD (left anterior descending artery) graft in patients with multivessel disease.

What is holding cardiac surgeons back from further adoption of multiarterial grafting? Greater technical complexity, longer operative time, wound healing concerns for patients with diabetes and latency in survival gains are among the reasons, according to an editorial published in *Innovations: Technology and Techniques in Cardiothoracic and Vascular Surgery* (2021;16[3]:209-213) by Cleveland Clinic cardiothoracic surgeons Faisal Bakaeen, MD, and Rami Akhrass, MD. To help close this practice gap and optimize success in this underutilized approach, the editorialists offer what they call "The 10 Commandments for Multiarterial Grafting."

"Multiarterial grafting may not be appropriate for all patients undergoing CABG, but it should be part of any revascularization strategy discussion," says Dr. Bakaeen. "Adhering to a few guiding principles helps ensure good early and late outcomes."

The 10 "commandments" are summarized below.

➤ 1) Use the left ITA to bypass the LAD

The left ITA-LAD graft is the mainstay of a CABG operation around which the remaining grafts are planned. The ITA is an ideal conduit: compared with the saphenous vein, it is rarely affected by intimal hyperplasia or atherosclerosis. And the LAD is the ideal recipient, usually supplying more than half of the mass of the left ventricle.

➤ 2) Choose a second arterial conduit for the second most important target

Make use of the ITAs carefully, with the aim of maximizing the amount of myocardium supplied by the grafts. Important target vessels are those that reach more than 75% toward the apex of the heart or supply a large territory via secondary branches. Various configurations are possible depending on patient anatomy and disease, but the overall strategy should be to use bilateral ITA and radial artery conduits for the largest territories at risk.

> **"Multiarterial grafting may not be appropriate for all patients undergoing CABG, but it should be part of any revascularization strategy discussion. Adhering to a few guiding principles helps ensure good early and late outcomes."** — Faisal Bakaeen, MD

➤ 3) Harvest the ITAs as a skeletonized graft

Carefully harvesting the ITAs as a skeletonized rather than pedicled graft is associated with better sternal healing and fewer wound complications. Sternal healing — and the decision whether to use both ITA conduits — is of particular concern in patients with diabetes, radiation exposure, use of steroids or immunosuppression, and/or poor nutritional status.

➤ 4) Assess graft patency intraoperatively

Intraoperative transit time flow measurement can help verify graft patency, providing the opportunity to promptly correct any problems. This is especially important for arterial conduits, which are more delicate than veins and susceptible to dissections and hematomas. The following thresholds indicate acceptable patency:

- Flow > 15 to 20 mL/min
- Pulsatility index < 3
- Back flow < 3%
- Diastolic filling of 60%-70% for left coronary targets, 50%-60% for right coronary targets

"False-negative and false-positive test results commonly occur for a variety of reasons," warns Dr. Bakaeen, who also wrote a recent invited expert opinion with Dr. Akhrass in *JTCVS Techniques* (2021;7:131-137) devoted to intraoperative graft patency measurement. "Ultimately, surgical judgment must be the primary driver of decisions about graft revisions."

➤ 5) Don't settle for a short or bad conduit

A good conduit is essential to optimal perioperative outcomes and long-term graft patency. Whichever blood vessel is chosen for a conduit, it should not be accepted if it has poor flow or is small, fragile or dissected. Short grafts under tension are liable to spasm, deformity and obstruction of native coronary flow. Radial arteries need particular attention, as about 25% are inadequate for grafting.

➤ 6) Avoid competitive flow

Attention is needed to avoid situations in which competitive flow may develop, resulting in a "string sign" on imaging. Competitive native flow can occur when grafting a coronary target that is not severely stenotic. Index flow reserve measurement can help determine whether a vessel needs to be grafted and which conduit would be appropriate. Radial arteries in particular tend to suffer from competitive flow and should not be used when the native target vessel is less than 90% stenotic. Competitive vein graft flow can also develop if a vein graft is placed close to an arterial graft with no significant disease between them.

➤ 7) Avoid steal

Either coronary-subclavian or coronary-coronary steal can lead to reversal of flow and worsening cardiac ischemia. Careful preoperative planning with bilateral arm blood pressure measurements and chest CT scans, as well as intraoperative flow measurements, can help avoid or detect such situations.

➤ 8) Go with parallel side-to-side anastomosis in sequential grafting

But beware sequential grafting with intramyocardial coronary vessels, where the myocardial tissue has a tendency to kink at the toe and heel, creating a "seagull deformity." It may be best to use a composite graft in such situations.

➤ 9) Perform CABG on-pump

Off-pump CABG should be reserved for procedures where minimal or no aortic manipulation is desired and for patients who have significant aortic calcification or are at increased risk from cardiopulmonary bypass.

➤ 10) Build volume-based experience

"Higher volumes of multiarterial grafting translate into better short- and long-term outcomes," says Dr. Bakaeen. "Experience should be built up in a stepwise fashion so it can become part of daily routine practice." ■

Contact Dr. Bakaeen at 216.444.0355 and Dr. Akhrass at 440.333.8600.

Artificial Intelligence Methodology Refines Cardiac Risk Stratification in Cancer Patients

Patient-patient network analysis proves to be fast and clinically intuitive

A machine learning technique using network clustering has been developed to assess risk of cardiac-related morbidity and mortality in oncology patients. The tool also identified serum levels of NT-proB-type natriuretic peptide (NT-proBNP) and troponin T as biomarkers associated with risk, offering an opportunity to recognize and target high-risk patients with appropriate preventive interventions.

This methodology and findings from analysis of data from thousands of Cleveland Clinic cancer patients with up to 20 years of follow-up were described in a recent article in *PLOS Medicine*.

"Our network clustering method allows rapid and clinically intuitive stratification of cardiac risk in cancer survivors," says one of the study's two corresponding authors, Patrick Collier, MD, PhD, Co-Director of Cleveland Clinic's Cardio-Oncology Center. "It promises to help identify patients at risk and clinically actionable factors for advancing precision medicine in cardio-oncology."

Cancer therapy and cardiac risk

While advances in cancer therapy continue to improve cancer outcomes, many patients face mounting cardiac risk from their lifesaving therapy, as cardiovascular effects have been demonstrated with radiotherapy, cytotoxic chemotherapy, targeted therapies and immunotherapy. Growing awareness of cancer therapy-associated cardiac dysfunction has launched the subspecialty of cardio-oncology, but little is understood about the impacts of the multiple variables involved, making risk assessment difficult.

Advances in artificial intelligence and network science technologies have enabled the development of tools that can derive clinically useful information from large datasets and many variables. In the current Cleveland Clinic study, a method was employed called *patient-patient similarity network-based risk assessment of cardiovascular disease* that allows for patients of unknown risk status to be classified based on their similarity to patients with known risk status.

Study design

The study was based on a cohort of 4,632 cancer patients referred to Cleveland Clinic's cardio-oncology service between March 1997 and January 2019. All had at least one of the following diagnosed cardiac outcomes: atrial fibrillation, coronary artery disease, heart failure, myocardial infarction or stroke. Patients were further categorized as having received the cardiac diagnosis before or after cancer therapy was initiated. Median patient age was 63 years (interquartile range, 54-71).

In addition to patient demographics, the analysis accounted for cancer type and stage, treatment type, laboratory test results, cardiac factors and more than 25,000 echocardiograms.

Four relevant subgroups, two significant biomarkers

Analysis of the data with patient-patient similarity network clusters identified four clinically relevant subgroups of patients that were statistically significantly correlated with incidence of poor cardiac outcomes and mortality.

One subgroup had the highest risk of de novo cancer therapy-related cardiac dysfunction (hazard ratio = 3.05; 95% CI, 2.51-3.72). Patients in this group had a higher risk of mortality within five years after initiating cancer therapies compared with long-term risk (i.e., 6-20 years).

"Our analysis determined that mortality was more likely within two to five years after the initiation of cancer therapy," notes Feixiong Cheng, PhD, the study's other corresponding author and a researcher in Cleveland Clinic's Genomic Medicine Institute. "This underscores the vital role of early cardiac care in improving the survival of cancer patients."

> **"Identification of clinically relevant predictors like these offers actionable biomarkers for rapid risk assessment that may ultimately promote early risk stratification in cardio-oncology practice."** — Patrick Collier, MD, PhD

In addition, clinical variable network analysis showed that mortality was significantly correlated with serum levels of two well-established biomarkers for heart disease:

- NT-proBNP, with a hazard ratio of 2.95 (95% CI, 2.28-3.82; $P < 0.001$) for levels > 900 pg/mL vs. 0-125 pg/mL
- Troponin T, with a hazard ratio of 2.08 (95% CI, 1.83-2.34; $P < 0.001$) for levels > 0.05 μg/L vs. ≤ 0.01 μg/L

"Identification of clinically relevant predictors like these offers actionable biomarkers for rapid risk assessment that may ultimately promote early risk stratification in cardio-oncology practice," says Dr. Collier.

Progressively sophisticated machine learning techniques

The study is the latest in a series from this team of investigators as they have developed the artificial intelligence method using the longitudinal Cleveland Clinic cancer database and applied it to issues in cardio-oncology.

In a paper published in the *American Journal of Cardiology* (2020;137:118-124), they detailed temporal trends of cardiovascular disease in oncology patients, finding that mortality and diagnosis of clinical cardiac disease peaked around the time of chemotherapy.

Another study (*Open Heart*. 2020;7[2]:e001412) focused on the relationship between atrial fibrillation and cancer. It found that a first diagnosis of atrial fibrillation among cancer patients was more common in older patients and those exposed to cardiotoxic treatment, and that it was associated with a poor prognosis.

A third study, published in the *Journal of the American Heart Association* (2020;9[23]:e019628), demonstrated for the first time that a large-scale machine learning-based approach provides an accurate and generalizable assessment of patient risk for cancer therapy-related cardiac dysfunction.

The current study extends this previous work and identifies clinically relevant subgroups correlated with incidence of cardiac outcomes, Dr. Collier notes. It also has identified two biomarkers associated with patient mortality, although the researchers stipulate that further validation is needed before these can be introduced in clinical practice.

Next steps

"Altogether, our findings indicate that, compared with traditional risk models, our patient-patient similarity network methodology is clinically intuitive and excels at integrating large-scale, heterogeneous patient data to stratify cardiac dysfunction risk in cancer patients," observes Dr. Cheng. "As a next step, we will be developing new risk calculators that integrate our artificial intelligence models into Cleveland Clinic's electronic health record system to improve cardiovascular care for cancer patients." ■

Contact Dr. Collier at 216.444.8429 and Dr. Cheng at 216.444.7654.

Non-Small Cell Lung Cancer Behaves Surprisingly Differently in Never-Smokers

Non-small cell lung cancer (NSCLC) — traditionally viewed as a disease of smokers — displays some key differences in patients who have never smoked, according to new data. Specifically, although never-smokers have better survival in stage I NSCLC than ever-smokers, they have more rapid disease recurrence and higher mortality in more advanced stages. Additionally, never-smoker NSCLC patients are more likely than their ever-smoker counterparts to be women, have disease in the lower lobe and have adenocarcinoma as the histopathologic subtype.

These findings, from an analysis of patients treated surgically for NSCLC at Cleveland Clinic, were reported in the *Journal of Thoracic and Cardiovascular Surgery* (2021;161[6]:1903-1917).

"The differences were pronounced enough that we must consider whether NSCLC is, at least in part, a distinct clinical entity in never-smokers," says co-author Sudish Murthy, MD, PhD, Section Head of Thoracic Surgery at Cleveland Clinic. "If so, it has potential ramifications for screening, diagnosis and treatment."

Teasing out differences

NSCLC is increasingly seen in people who have never smoked. The Cleveland Clinic study was designed to identify differences between never-smokers and ever-smokers with NSCLC in terms of demographics and cancer characteristics. Prior evidence indicates that gene mutations and molecular profiles in lung cancer differ between never- and ever-smokers, supporting the hypothesis that the disease is different at an underlying level between the two groups.

Patients who underwent pulmonary resection for NSCLC at Cleveland Clinic between January 2006 and July 2016 were included; 172 (11%) were never-smokers and 1,376 (89%) were ever-smokers. The two cohorts were matched by patient characteristics, histopathologic cancer cell type and pathological stage. A weighted balancing score was used to compare survival and cancer recurrence, and machine learning was used to identify differences related to individual characteristics.

Compared with their ever-smoker counterparts, never-smokers with NSCLC were (1) more likely to be women (63% vs. 45%); (2) less likely to have upper-lobe disease (53% vs. 62%); and (3) more likely to have adenocarcinoma (88% vs. 62%).

Among matched pairs, never-smokers had greater survival at five years in pathological stage I compared with ever-smokers (96% vs. 78%) but lower survival at five years in stage II (54% vs. 78%). Additionally, freedom from cancer recurrence at five years was lower among never-smokers (68% vs. 79%), with recurrence among patients with stage II NSCLC driving the difference.

Several factors — tumor size, lymph node burden and histopathologic cell type — were more predictive of cancer recurrence and death among never-smokers versus ever-smokers.

What the findings may mean

"The differences in NSCLC in never-smokers, particularly in terms of outcomes for stage II disease, suggest unique tumor or host behaviors may be at play," says co-author Usman Ahmad, MD, a Cleveland Clinic thoracic surgeon.

He and his colleagues write that their findings highlight the need for further research and may argue for the following:

- Public health measures to screen for NSCLC regardless of smoking history. Never-smokers now constitute up to 15% of newly diagnosed lung cancer patients, yet they are not offered screening to detect occult NSCLC, which is routine for smokers.
- More genetic and molecular research on NSCLC in never-smokers. Prior research indicates that certain gene rearrangements, more common in never-smokers, are associated with reduced efficacy of platinum-based chemotherapy and immune checkpoint inhibitors. Cleveland Clinic now tests all tumors for known activating mutations, which promises to accelerate initiation of optimally informed therapy.
- More differentiation between never- and ever-smokers in clinical research. Some studies have already found that drug efficacy varies by proportions of never-smokers enrolled.
- Incorporation of smoking history into NSCLC staging and treatment algorithms. As understanding grows, smoking history may become a factor in management, with more-aggressive treatment indicated for advanced disease in never-smokers.

"As precision medicine advances, new algorithms can be expected to more accurately guide prognosis and optimize treatment strategies," Dr. Murthy says. "Smoking history may one day be a standard factor in such tools."

Contact Dr. Murthy at 216.444.5640 and Dr. Ahmad at 216.444.1921.

Research Roundup: Recaps of Recent Studies of Note From Cleveland Clinic

5 Years of a Comprehensive STEMI Protocol and Its Associations With Sex Disparities

➤ *Eur Heart J Open.* 2021 Aug 20 (Epub ahead of print)

Adopting a comprehensive protocol for ST-elevation myocardial infarction (STEMI) may help close the persistent gender gap in STEMI care, suggests this observational cohort study. Researchers compared outcomes and quality measures of STEMI patients for 3.5 years before (n = 723) and five years after (n = 1,110) Cleveland Clinic's July 2014 implementation of a protocol to reduce variability in STEMI management. All outcomes — use of guideline-directed medical therapy, door-to-balloon time, use of transradial PCI, in-hospital mortality, major adverse cardiac/cerebrovascular events and net adverse events — improved substantially after STEMI protocol implementation. Notably, improvements in all measures were most pronounced in female patients, to the point that differences between the sexes — which previously significantly favored men over women on all measures — were reduced to nonsignificant levels on all measures but one. "STEMI protocols modeled after [this one] may offer the potential to improve the outcomes of women with STEMI," the authors conclude. ■

Performance of First Pacemaker to Use Smart Device App for Remote Monitoring

➤ *Heart Rhythm O2.* 2021 Aug 2 (Epub ahead of print)

Remote monitoring of patients' cardiac implantable electronic devices (CIEDs) promotes improved patient outcomes, but adherence to remote monitoring has been unsatisfactory to date. Now an international study led by Cleveland Clinic finds that the success rate of scheduled remote monitoring transmissions can be significantly improved when CIEDs are linked with patients' own smart devices for direct communication via an app. In the prospective study, patients using the app-based approach (n = 245) achieved a successful completion rate of 94.6% for scheduled data transmissions over 12-month follow-up. This was significantly higher than the transmission success rates (56.3% to 87.1%) among matched patients using either manual or wireless communication via bedside console. Patient surveys found good patient acceptance of the app-based approach, which the authors say can positively reshape the care of patients with CIEDs by improving the success of remote monitoring. ■

Meta-Analysis of Endovascular Abdominal Aortic Repair in Large-Diameter Infrarenal Necks

➤ *J Vasc Surg.* 2021;74:309-315

A wide proximal aortic neck appears to put patients at greater risk for complications and death following endovascular aneurysm repair (EVAR) for treatment of abdominal aortic aneurysm (AAA). So concludes a systematic literature review and meta-analysis by Cleveland Clinic researchers. They evaluated outcomes of 7,448 patients treated for AAA with EVAR across 11 published trials that met PRISMA inclusion criteria. Of this cohort, 26.9% had wide aortic necks, defined as a diameter of 25-30 mm (depending on the study) or greater. Weighted averages of composite major adverse events and aneurysm-related mortality were greater in the group with wide aortic necks (33.5% and 15.3%, respectively) than in patients with normal diameters (21.2% and 3.9%, respectively). Also, risks of aneurysm rupture, aneurysm sac enlargement and type I/Ia endoleaks were significantly higher in patients with wide aortic necks. The authors conclude that while EVAR remains an option for AAA in patients with wide aortic necks, particularly when open repair is unfeasible, close long-term surveillance is paramount to stem potentially catastrophic complications. ■

Mitral Annular Calcification and Valvular Dysfunction: Multimodality Imaging Grading

➤ *Eur Heart J Cardiovasc Imaging.* 2021 Sept 9 (Epub ahead of print)

As the population ages, the clinical impact of mitral annular calcification (MAC) looms large due to its various pathophysiologic manifestations. Despite this impact, there is no universally accepted grading system for MAC severity. To fill that gap, Cleveland Clinic experts developed a novel multiparametric grading system for MAC as outlined in this journal article. The system is based on echocardiographic evaluation, cardiac CT quantification and assessment of special clinical features associated with MAC. It is designed to allow for reproducible quantitative grading of MAC severity and associated mitral valve dysfunction that can be used to improve risk stratification, selection of patients for surgical and transcatheter interventions, and preprocedural planning. ■

continued next page

Canakinumab for COVID-19-Associated Cardiac Injury and Heightened Inflammation

➤ *Eur Heart J Open*. 2021 July 29 (Epub ahead of print)

The monoclonal antibody canakinumab does not accelerate clinical improvement within two weeks among patients with COVID-19-associated myocardial injury and increased inflammation, finds this phase 2 study by Cleveland Clinic researchers. However, the trial revealed no safety concerns and provides support for studies of high-dose canakinumab for potential efficacy benefits at four weeks after infusion. Forty-five patients hospitalized with COVID-19 who had evidence of myocardial injury (troponin > 99th percentile of upper reference limit) and a C-reactive protein concentration above 50 mg/L were randomized in a double-blind manner to a single IV infusion of canakinumab 300 or 600 mg or placebo. There were no between-group differences in the primary endpoint of clinical improvement at 14 days, but there was a trend toward greater rates of improvement with the 600 mg canakinumab dose at 28 days. "Future studies should focus on high-dose canakinumab in the treatment arm and assess efficacy outcomes at day 28," the authors conclude. ■

WRAP-IT Substudies Yield Insights on Maximizing Value of Antibacterial Envelope for CIEDs

➤ *JACC: Clin Electrophysiol.* 2021 Sept 29 (Epub ahead of print)

➤ *Heart Rhythm.* 2021 July 16 (Epub ahead of print)

In 2019, the landmark WRAP-IT trial showed that placing cardiac implantable electronic devices (CIEDs) inside an absorbable, antibiotic-eluting envelope reduced the incidence of major infection by 40% within 12 months after CIED replacement/upgrade/revision or de novo implantation. Since then, multiple substudies of the multicenter trial — whose leadership includes two Cleveland Clinic electrophysiologists — have delved deeper into CIED infection and prevention. One recent substudy showed that several modifiable procedural factors in secondary CIED procedures correlated with infection risk, which may lead to practice changes around use of capsulectomy, perioperative antibiotic choice and skin preparation agents. Another substudy showed that major infection was dramatically increased in patients who developed hematoma and that risk of hematoma-associated infection was significantly lower in CIED patients who received the antibiotic envelope compared with controls who did not. ■

Gut Microbes Impact Stroke Severity via the Trimethylamine *N*-Oxide Pathway

➤ *Cell Host Microbe*. 2021;29:1199-1208.e5

Preclinical findings from Cleveland Clinic researchers show for the first time that the gut microbiome impacts stroke severity and functional impairment following stroke. Investigators transplanted fecal material from human subjects with high and low levels of the gut metabolite TMAO (trimethylamine *N*-oxide) into germ-free mice. They also performed parallel experiments using defined microbial communities genetically engineered with or without the ability to make the precursor of TMAO. Over time, recipients of microbes from subjects with elevated TMAO levels (or synthetic communities that can make the TMAO precursor) were found to have significantly more TMAO in their blood. Higher blood TMAO levels were associated with more extensive brain damage in multiple stroke models and greater motor and cognitive functional deficits following stroke. Also, dietary manipulations to alter TMAO levels impacted stroke severity, as higher TMAO blood levels were associated with larger cerebral infarct size. The results lay the groundwork for potential new interventions to help treat or prevent stroke, the researchers note. ■

Quality Assessment of Published Systematic Reviews in High-Impact Cardiology Journals

➤ *Front Cardiovasc Med.* 2021;8:671569

The synthesis and reporting of systematic reviews in top-tier cardiology journals has been marked by serious and widespread quality gaps over the past decade, concludes this analysis by a Cleveland Clinic-led research team. The authors searched PubMed for all systematic reviews published from 2010 to 2019 in the five cardiology journals with the highest impact factor: *Circulation*, *European Heart Journal*, *Journal of the American College of Cardiology*, *Circulation Research* and *JAMA Cardiology*. Analysis of the 352 eligible reviews found that over 70% of them ranked as low or critically low in quality on the AMSTAR tool for assessing systematic review quality. The researchers write that their findings underscore the need for "rigorous editorial and peer-review policies in systematic review publishing" and enhanced education among clinicians and researchers on interpreting evidence. ■

➤ CME PREVIEW

CME SUMMIT OFFERS ESSENTIALS IN LIFELONG MANAGEMENT OF ADULT CHD

Comprehensive Care for the Lifetime Treatment of Adult Congenital Heart Disease: A Case-Based Approach

April 22-23, 2022
Sheraton Grand Chicago | Chicago, Illinois
Information/registration: ccfcme.org/achd22

Progress in the management of congenital heart disease (CHD) has meant that more patients than ever are surviving into adulthood and enjoying long, active life spans. That success has markedly increased demand for specialty care in adult CHD — and the need for knowledge of adult CHD among those in the general cardiovascular care community.

In response, Cleveland Clinic is pleased to announce the debut offering of "Comprehensive Care for the Lifetime Treatment of Adult Congenital Heart Disease," a CME summit designed to meet that need for knowledge among cardiologists, cardiothoracic surgeons and others caring for adults with CHD.

"As children with congenital heart disease age, their risk of related complications increases as adults," says course co-director Lars Svensson, MD, PhD, Chair of Cleveland Clinic's Heart, Vascular & Thoracic Institute. "Lifelong surveillance is paramount in this population, and this new course aims to prepare all cardiovascular clinicians to help provide optimal care for this population as they face new challenges as adults."

"This course is a unique opportunity for all involved in the care of adult CHD patients," adds course co-director and pediatric and congenital heart surgeon Tara Karamlou, MD, MSc. "It couples discussions of challenging clinical scenarios — such as the failing Fontan, complex valve strategies and management of anomalous aortic origin of the coronary artery — with patient perspectives and health-related quality-of-life issues. Attendees will be immersed in learning about the lifelong care of this growing population through a comprehensive lens that considers patients' emotional, social and physical needs."

Wide-ranging content across a day and a half

The summit runs a full day on Friday, April 22, and until noon on Saturday the 23rd.

The summit starts with an overview of adult CHD that includes patient perspectives and an exploration of the value of Adult Congenital Heart Association accreditation. The program then dedicates multipresentation sessions to each of the following major areas of adult CHD:

- Pulmonary valve disease, including tetralogy of Fallot and other lesions
- Single-ventricle defects
- Systemic right ventricle, including congenitally corrected transposition of the great arteries and dextro-transposition of the great arteries

The above areas are explored from multiple perspectives, including imaging, interventional cardiology, cardiac surgery and electrophysiology.

An additional session addresses heart failure, pulmonary hypertension and palliative care in adult CHD, and the concluding session profiles ongoing research in adult CHD, looks toward future developments in the subspecialty and explores revealing case studies. Lunch on Friday features a session devoted to patient perspectives and pregnancy and mental health in adults with CHD.

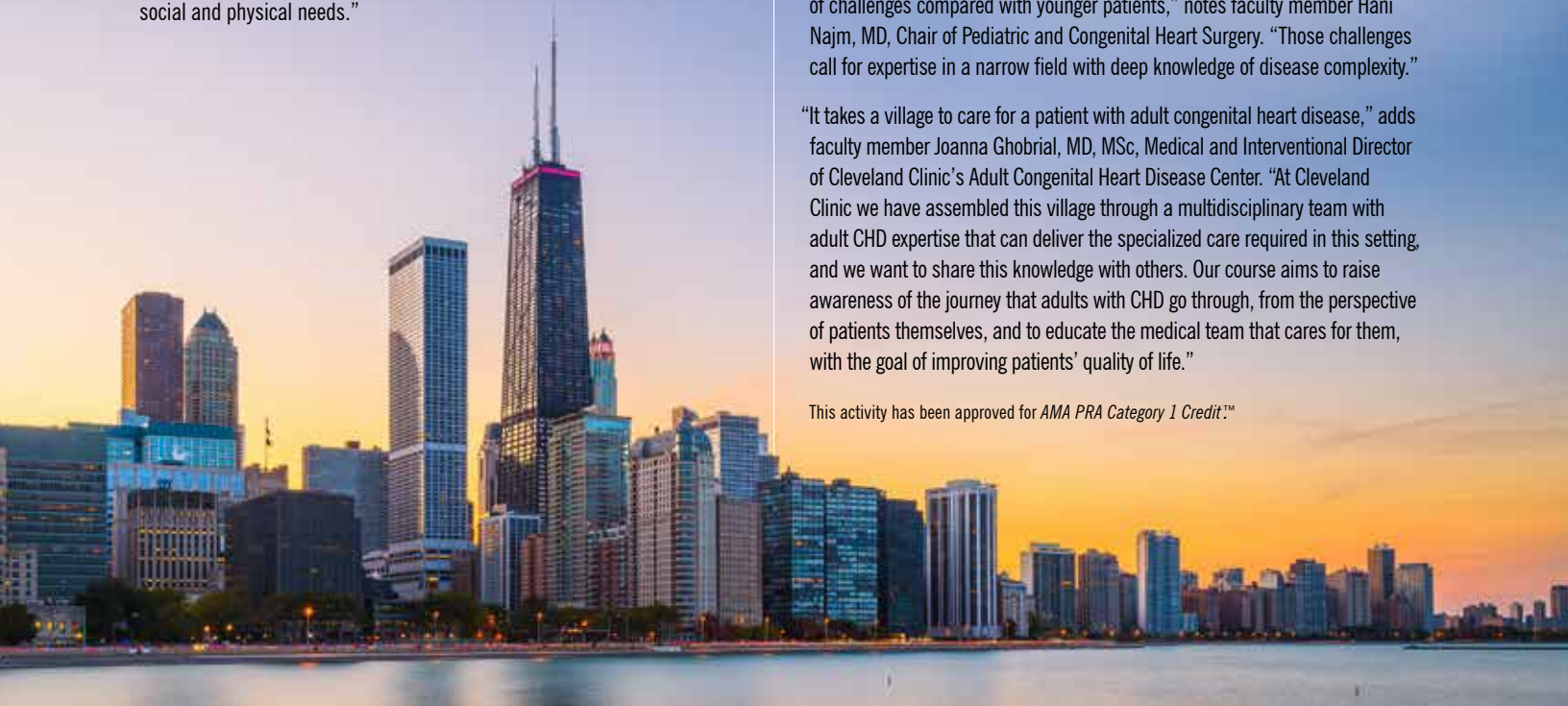
Content will be well-paced, with most presentations lasting 15 or 20 minutes and formats alternating between lectures, case presentations, Q&A sessions and panel discussions. Faculty will include medical, surgical and interventional experts in adult CHD from Cleveland Clinic and several other leading centers in the U.S. and Canada.

It takes a village

"Management of adults with congenital heart disease presents a different set of challenges compared with younger patients," notes faculty member Hani Najm, MD, Chair of Pediatric and Congenital Heart Surgery. "Those challenges call for expertise in a narrow field with deep knowledge of disease complexity."

"It takes a village to care for a patient with adult congenital heart disease," adds faculty member Joanna Ghobrial, MD, MSc, Medical and Interventional Director of Cleveland Clinic's Adult Congenital Heart Disease Center. "At Cleveland Clinic we have assembled this village through a multidisciplinary team with adult CHD expertise that can deliver the specialized care required in this setting, and we want to share this knowledge with others. Our course aims to raise awareness of the journey that adults with CHD go through, from the perspective of patients themselves, and to educate the medical team that cares for them, with the goal of improving patients' quality of life."

This activity has been approved for *AMA PRA Category 1 Credit™*.



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Information/registration: ccfcme.org/achd22
(see page 19 for a detailed preview)

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