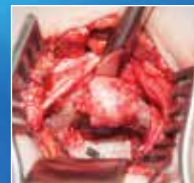




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Gaining steam with
more patients, new uses

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Dear Colleagues:

As we put together this issue of *Cardiac Consult*, we were struck by just how wide-ranging our discipline of cardiovascular healthcare has become.

In just the handful of articles in this issue, specialists from across Cleveland Clinic's Sydell and Arnold Miller Family Heart & Vascular Institute share practical insights on everything from the nuances of cardiac imaging studies in asymptomatic competitive athletes (pp. 3 and 4) to the singular surgical expertise needed to astutely manage the varied manifestations of thoracic outlet syndrome (p. 13).

Along the way we visit topics that may be more standard fare in cardiovascular care — like the evolution of transcatheter valve repair and replacement (p. 6) and how to counsel patients about a heart-healthy diet in the wake of shifting evidence (p. 9) — but there's no denying that the scope and reach of our specialty are expanding. Just consider the swift development of cardio-oncology or the increasing contributions we are making to the understanding and management of vasculitic diseases.

In this context, Cleveland Clinic's high-volume cardiovascular practice presents a number of opportunities. It allows us to build experience in rare procedures and unusual conditions, thereby further expanding the potential reach of our specialty. For common procedures and conditions, it allows us to perform outcomes analyses of huge patient cohorts for research and quality-improvement purposes. Finally, the breadth of our practice enables us to experiment with new operational and IT processes that can easily be scaled if and when they prove successful.

In recent years, our Heart & Vascular Institute has increasingly been sharing the benefits from these opportunities with partner provider groups across the country via a growing number of alliance, affiliation and consulting relationships. On p. 17 we introduce a new article series, "Case Studies in Collaboration," that will profile how we've worked with specific allied and affiliated providers to help them improve a given aspect of their clinical or operational functions. This first installment showcases our collaboration with MedStar Heart & Vascular Institute to create an integrated and centralized cardiovascular registry information flow.

Our discipline has grown too broad and complex for any of us to tackle its challenges alone. If you see an opportunity for collaboration based on anything you find in this issue, please be sure to contact us (emails are in the column to the right) or our Cleveland Clinic colleagues cited in the individual articles that follow.

Respectfully,

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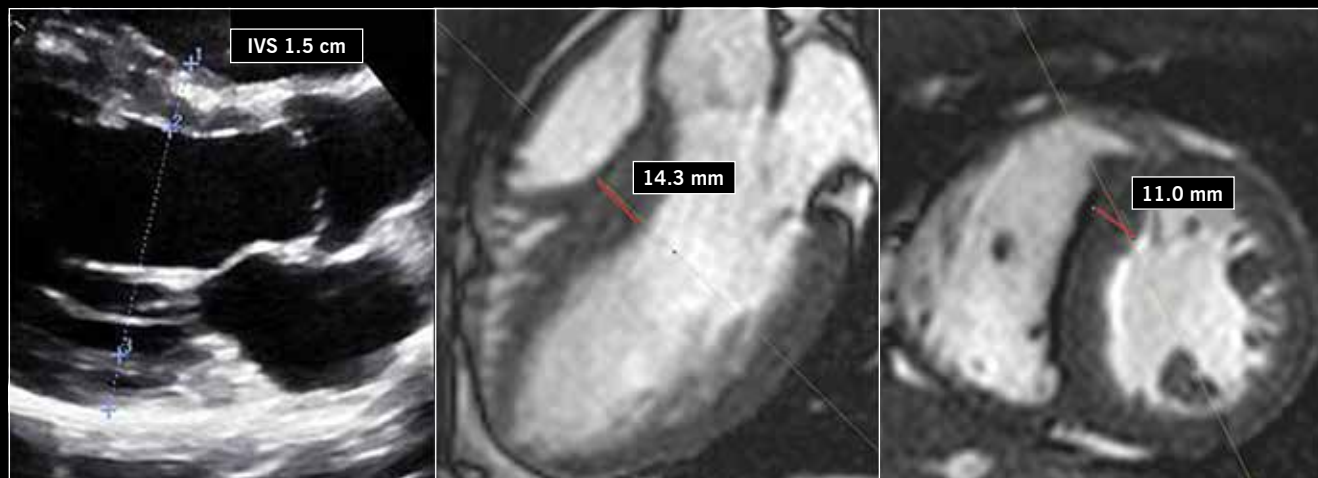
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Image of the Issue



BY DERMOT PHELAN, MD, PhD

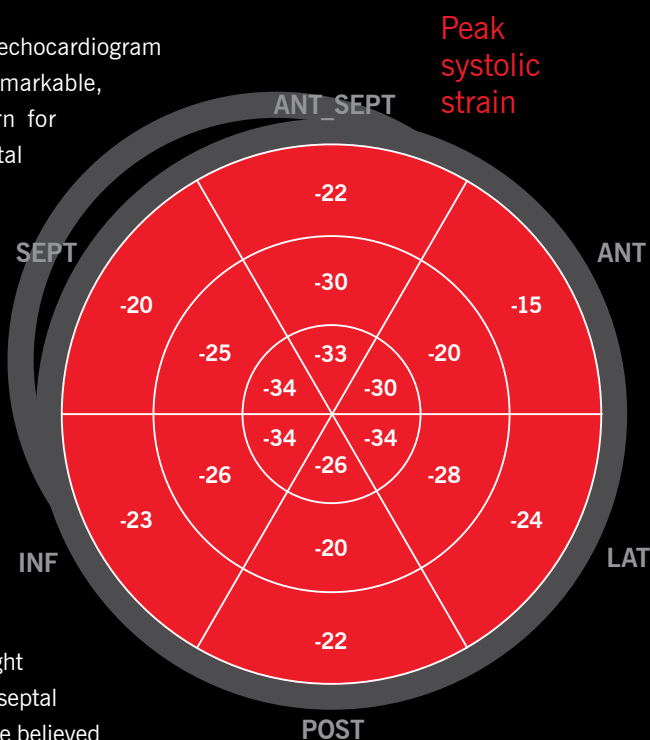


SEPTAL WALL SUBTLETIES IN A YOUNG ATHLETE

A white male high school basketball player undergoes an ECG and echocardiogram after presenting with atypical chest pain. Although the ECG is unremarkable, he is disqualified from competitive sports because of concern for hypertrophic cardiomyopathy (HCM) after the echo reveals septal wall thickness of 1.5 cm. He has no family history of HCM.

He comes to Cleveland Clinic's Sports Cardiology Center for a second opinion. The septal wall measurements are confirmed on echocardiogram (above left image). While up to 18 percent of African-American athletes have septal wall thickness greater than 12 mm, this finding is unusual in a white athlete. However, diastolic function and longitudinal strain are normal (figure at right).

He performs well on a metabolic stress test (VO_2 max is 64.3 mL/kg/min), and MRI reveals no scar and a normal mitral valve apparatus. Close evaluation of the MRI reveals that the septal measurement from long-axis view was overestimated due to a tangential cut through the septum and inclusion of right ventricular trabeculation (middle and right images above). The true septal measurement is determined to be 11 mm. The collective findings are believed to be related to "athlete's heart," and the patient is allowed to return to play. ■



FOR MORE INFORMATION, SEE NEXT PAGE OR CONTACT DERMOT PHELAN, MD, PhD, AT PHELAND@CCF.ORG.



Making Sense of the Athlete's Heart

For serious athletes, not all physiologic changes on imaging require detraining or quitting the sport.

Athlete's Heart: A Common Case Scenario

On a hot summer day, a young African-American competitive cyclist grew dizzy with maximal exertion while training. His performance dropped. Examination by a cardiologist revealed a normal ECG, but his echocardiogram was concerning for hypertrabeculation at the left ventricular (LV) apex. Metabolic stress testing showed good exercise capacity. MRI confirmed a heavily trabeculated left ventricle but normal LV function. The ratio of noncompacted to compacted myocardium was $> 2.3:1$. He was diagnosed with LV noncompaction, commenced on a low-dose beta-blocker and disqualified from competitive sports.

He sought a second opinion from Cleveland Clinic and was referred to Dermot Phelan, MD, PhD, Director of the Sports Cardiology Center. Prominent LV trabeculations were confirmed, but there were no other features concerning for LV noncompaction: no scar on MRI, no abrupt transition zone from normal to thin compacted myocardium, normal strain and torsion, and no family history of cardiomyopathy. Dr. Phelan determined that the changes were a normal variant often seen in athletes, particularly those of African-American descent, and that the dizziness was not cardiac in origin. He diagnosed "athlete's heart" and gave the patient permission to resume competitive cycling.

The Need for Nuanced Evaluation

Every year, about 100 U.S. athletes — student, amateur and professional — die of sudden cardiac death. Each fatality brings renewed interest in preventing such tragedies through early identification of underlying pathologies. Yet the methodologies and guidelines used to ascertain risk in young, asymptomatic individuals are weak, as are those for differentiating effects of strenuous exercise on the heart from potentially lethal heart diseases.

At Cleveland Clinic's Sports Cardiology Center, multiple specialists focus on the health of amateur and pro athletes of all ages. The team, led by Dr. Phelan, a cardiac imaging specialist, includes:

- Cardiologists with subspecialty expertise ranging from electrophysiology to prevention to heart disease in women
- Cardiothoracic surgeons interested in aortopathies and coronary anomalies
- Exercise physiologists
- Sports pulmonologists
- Dietitians
- Psychologists

The center works with the Cleveland Clinic Center for Sports Health in the Department of Orthopaedic Surgery, which provides care for Cleveland's professional baseball and basketball teams and conducts health screenings for high school and college teams. "When our colleagues see athletes with concerning symptoms such as fainting, dyspnea, chest pain or a drop in performance — or if an athlete has a murmur or a worrisome family history — they refer to us for evaluation," says Dr. Phelan.

Recognizing Athlete's Heart

Specialists at the Sports Cardiology Center face two challenges on a regular basis:

- Determining whether the heart of an asymptomatic athlete is healthy enough to withstand the stresses of a sport
- Diagnosing the underlying cause of symptoms in an athlete with heart disease

In both cases, the athlete's future — and sometimes life — depends on the findings.

Athletes are subject to the same diseases and anomalies that can cause sudden cardiac death or heart failure in the general population. However, their hearts also undergo physiologic changes from the stresses caused by regular strenuous exertion, resulting in the nonpathological entity known as athlete's heart. Dr. Phelan knows which tests differentiate exertion-induced physiologic changes from those produced by potentially lethal pathologies.



“The vast majority of findings in asymptomatic athletes are false positives. We rarely rely on a single test.” — Dermot Phelan, MD, PhD

“These sports-related changes to the heart are often particular to age, race, sex and type of sport,” he says. “All can have completely different ranges of normal. Most patients attending cardiology outpatient clinics are older and may be inactive, so when physicians encounter an enlarged ventricle wall or cavity, they naturally think it’s a real problem. But if the patient is an athlete, the findings may simply be normal structural changes caused by ongoing stress to the heart.”

All About Integrating Results

Because the prevalence of heart diseases in athletes is very low, choosing the appropriate tests for asymptomatic patients requires unique skills and expertise, plus an understanding of the demands of the sport and training techniques.

Sports Cardiology: Beyond the Young and Healthy

Athletic participation is not confined to the young and healthy. A large part of the sports cardiologist’s role is managing athletes with confirmed cardiac disease, young or old.

“There are many athletes with heart disorders who wish to return to the sport they love,” says Dr. Phelan. “They may have a bicuspid aortic valve or a dilated aorta or have undergone open-heart surgery for coronary or valve disease. Many physicians have no experience advising such patients and understandably take the safe course of stringent restrictions when in reality many of these people would be better off exercising in some capacity. We individualize our advice but often allow the athlete far more freedom to exercise.”

“The probability of accurately identifying the pathology is highly dependent on the test’s specificity,” says Dr. Phelan. “We are cautious in interpreting test results, because the vast majority of positive findings in asymptomatic athletes are false positives. Understanding that leads one to do further testing and integrate the results for a full overview. We rarely rely on a single test.”

Diagnosing heart disease in symptomatic athletes requires a different approach. “We assess the patient and see if our findings relate to the symptoms,” he says. “A careful history will tell us whether we should be worrying.”

Once a diagnosis is made or an underlying problem corrected, cardiac exercise physiologist Gordon Blackburn, PhD, designs an individualized exercise program that’s safe for the athlete and effective for the sport. “Our primary goal is to protect the heart, whether the patient is cleared to return to competition and training or directed toward noncompetitive activities,” Dr. Blackburn explains.

On the Horizon: Rewriting the Guidelines

Existing guidelines for treating athletes are limited and based primarily on expert opinion. Without supportive data, they tend to err toward caution and often advise detraining or quitting the sport. Experience enables Dr. Phelan to know when it’s safe to go outside the guidelines. “Guidelines are not firm rules,” he says. “Detraining has been shown to work in small published studies, but it’s rarely necessary.”

Sports cardiology expertise can be invaluable in controversial areas, such as whether an athlete with a defibrillator or LV non-compaction can return to play. “We discuss the pros and cons with the athlete and make a decision together,” says Dr. Phelan.

The accumulation of test results and treatment outcomes is helping build a body of evidence that can eventually be used to rewrite the guidelines — likely with a major impact on how competitive athletes of all ages are managed. “The next five years should bring more robust data on what’s safe and who should and shouldn’t be allowed to train,” Dr. Phelan concludes. ■

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Transcatheter Valve Repair and Replacement: Gaining Steam with More Populations, New Applications

Both aortic and mitral valve therapies expand through new percutaneous approaches.

In less than a decade, transcatheter aortic valve replacement (TAVR) has developed into an established procedure for restoring valve function in inoperable patients and those at high surgical risk, with promising potential for use in less-sick populations. Similarly, a percutaneous technique for mitral valve repair has been approved for clinical use, and transcatheter mitral valve replacement is now being explored.

In their most fundamental applications, these percutaneous approaches to valve therapy provide more options for treating inoperable patients with valve diseases. “Now that there are alternatives, we don’t have to give these patients bad news,” says cardiothoracic surgeon Lars G. Svensson, MD, PhD, Chair of Cleveland Clinic’s Miller Family Heart & Vascular Institute.

But the latest in the trend toward transcatheter valve therapies is their application to expanding populations and indications. Cleveland Clinic surgeons and cardiologists see a rosy future for these approaches — and they are helping shape that future on multiple fronts.

A Decade of Progress in TAVR

Work with TAVR at Cleveland Clinic dates back to early explorations of the technology in 2004 by Dr. Svensson and others. Cleveland Clinic became involved in TAVR trials in 2006, and its cardiologists and surgeons continue to evaluate various transcatheter approaches to aortic and mitral valve procedures.

“With every procedure we do, I’m left with a sense of excitement and appreciation of the technology,” says interventional cardiologist Amar Krishnaswamy, MD. He calls TAVR one of the most exciting developments in the history of interventional cardiology. “It has changed the paradigm for treating aortic stenosis — as well as whom we treat.”

Cleveland Clinic interventional cardiologists and cardiac surgeons collaborate on an average of eight TAVR cases per week. At 0.4 percent, Cleveland Clinic’s mortality rate is far below the national average of 4 to 6 percent. Intervention-

al cardiologist Samir Kapadia, MD, attributes this success to a team approach. “It’s a necessity for good outcomes,” he says.

Today, Dr. Kapadia and his colleagues perform many TAVR cases without intubation or general anesthesia, using conscious sedation and pain medications. “Recovery is much easier,” he explains.

The Expanding TAVR Patient Pool

TAVR was developed as an option for extreme-risk, inoperable patients. Five-year results of the PARTNER 1B trial, which compared TAVR with medical treatment in this population, were presented at this year’s annual scientific session of the American College of Cardiology (ACC) and simultaneously published in *The Lancet* (2015 Mar 15). In this study, TAVR resulted in a 22 percent survival benefit and a 28 percent reduction in cardiovascular mortality compared with standard treatment.

“This was the first — and will probably be the only — randomized aortic stenosis trial that includes a standard treatment group, since its results make it unethical to treat severe aortic stenosis with medical therapy alone without aortic valve replacement,” says Dr. Kapadia, lead author of the PARTNER 1B report.

Its sister trial, PARTNER 1A, assessed TAVR in another population — patients with aortic stenosis at high surgical risk — and found TAVR to be equivalent to surgical aortic valve replacement in all parameters. Five-year results were also presented at ACC 2015 and published in *The Lancet* (2015 Mar 15).



8

Cleveland Clinic's average
weekly TAVR caseload

0.4%

Cleveland Clinic's TAVR
mortality rate

"The rigorous trial performance and comparative effectiveness analyses of adjudicated end points give us confidence that in high-risk surgical patients, there is no advantage to surgical valve replacement over TAVR as far as risk of death," says Dr. Svensson, a key co-investigator in PARTNER 1A.

Cleveland Clinic has proceeded to using TAVR in patients at intermediate surgical risk through participation in the multi-center PARTNER 2A trial, which is randomizing such patients to surgery or TAVR. Results have not yet been published, but Dr. Krishnaswamy notes that European data on TAVR in this population have been encouraging.

Remaining Challenges in TAVR

TAVR can be performed via a transfemoral, transapical, transaortic or subclavian approach, but as delivery catheters become smaller, more patients can be treated via the less-invasive transfemoral route. "The ability to perform procedures in smaller arteries allows us to bring the technology to a larger group of patients with lower rates of stroke and vascular complications," says Dr. Krishnaswamy.

Several issues with TAVR have yet to be resolved, including the need for post-procedure pacemakers in 5 to 25 percent of patients (depending on the type of valve used). But of all complications, paravalvular leak may be the most serious: The more severe the leak, the greater the risk of death and symptoms.

Cleveland Clinic is involved in clinical trials of three repositionable transcatheter valve devices designed to reduce paravalvular leaks, reduce the risk of vascular complications and provide access through a vessel as small as 5.5 mm. Interventional cardiologist E. Murat Tuzcu, MD, is national principal investigator (PI) of a trial testing the effectiveness of Direct Flow Medical's recapturable and repositionable device for minimizing paravalvular leaks.

An additional safety issue is the risk of stroke with TAVR, which remains at 2.5 to 3 percent — higher than with surgical valve replacement. Yet placement of a filter in the carotid arteries at the time of TAVR may reduce stroke risk, a strategy embraced by developers of several investigational embolic protection systems.

Dr. Kapadia is national PI of a study using one such filter system, developed by Claret Medical. "This is an important step forward, because preventing strokes in this way may yield a lower stroke risk than with surgery," he says.

Valve-in-Valve TAVR Promises More Progress for Riskiest Patients

TAVR advocates are increasingly implanting the prosthesis inside a failed surgical bioprosthetic valve — a technique called valve-in-valve TAVR that looks promising for patients considered at high or extreme risk from open-heart surgery.

"Valve-in-valve TAVR can be a lifesaving option for these patients," says Dr. Tuzcu, who has extensive experience with the procedure. "They should be offered the opportunity to participate in clinical studies."

Information on valve-in-valve TAVR from three registries and from off-label use has confirmed that the size and type of prosthesis, the aortic root anatomy and the underlying pathology are important outcome determinants.

"A new valve allows only a limited opening if the size of the failed surgical prosthesis is small, and this can be an issue," Dr. Tuzcu notes. "Additionally, some devices leave too little space between the prosthesis and the coronary arteries supplying the myocardium."

continued next page ➤



“Whereas the past decade was the decade of TAVR, the coming years will be the decade of transcatheter mitral valve replacement.”

— E. Murat Tuzcu, MD



Advances in Mitral Valve Repair Too

Although most efforts to repair the mitral valve through a catheter have failed so far, Abbott Vascular's MitraClip® has bucked the trend, gaining FDA approval in late 2013 for treatment of severe degenerative mitral regurgitation (MR) in patients at high surgical risk. The device imitates a surgical technique called the Alfieri stitch, which improves approximation of the leaflets.

When applied to the right patient, MitraClip can provide functional and quality-of-life improvements. Cleveland Clinic performs one or two MitraClip repairs per week.

“In patients who are good surgical candidates, surgery for degenerative MR is the gold standard,” says Dr. Krishnaswamy. “For those degenerative MR patients at high risk for complications from surgery, MitraClip is a safe and effective alternative.”

Assessing MitraClip in Functional Regurgitation

Most European experience with MitraClip was not in degenerative MR but rather in patients with functional MR. In these patients, MitraClip can produce durable reductions in regurgitation, left ventricle size, NYHA class and heart failure admissions.

“These patients have sicker hearts,” explains Dr. Krishnaswamy. “For them, surgery is riskier and does not always produce a durable result. Having an alternative strategy is imperative, and MitraClip fulfills that need.”

The COAPT trial, which began enrolling in 2014 with Dr. Kapadia as Cleveland Clinic's site PI, is randomizing patients with functional MR to medical therapy or MitraClip. Results should be available in two years.

About 15 additional percutaneous mitral valve repair devices are in development, but there are no plans to test them in the U.S. at this time.

The Decade of Transcatheter Mitral Valve Replacement?

The next frontier may well be transcatheter mitral valve replacement (TMVR). “Whereas the past decade was the decade of TAVR,” says Dr. Tuzcu, “the coming years will be the decade of TMVR.”

Feasibility studies of several TMVR options will begin in the U.S. this year. Cleveland Clinic is participating in initial studies of the Tendyne Bioprosthesis Mitral Valve, which is implanted transapically in highly symptomatic patients with MR who are considered inoperable or at high surgical risk.

As percutaneous devices improve, transcatheter approaches may be applied to larger patient populations, although surgery remains the gold standard for treating most patients with degenerative MR.

“We perform the surgery robotically, with a small incision and no sternotomy, and achieve a nearly perfect repair in all patients,” notes cardiothoracic surgeon A. Marc Gillinov, MD. “The operative risk is 1 in 1,000.”

“The aim of the TMVR techniques is to offer options to patients who are not good candidates for surgical treatment,” adds Dr. Tuzcu.

A Field in Motion

With the field of transcatheter valve repair and replacement progressing quickly, Cleveland Clinic plans to remain at the fore of testing and development.

“The results of our experience have been exciting,” observes Dr. Krishnaswamy. “We're amazed at what can be done through an almost invisible incision in the top of the thigh.” ■

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and Heart Disease:

A Roundup of Advice Ripe for Rethinking

Science doesn't like dogma, especially when it comes to diet and heart disease. Research continually refines what we know about links between what our patients eat and their cardiovascular health. Indeed, the new *Scientific Report of the 2015 Dietary Guidelines Advisory Committee* commissioned by the U.S. government includes some surprising departures from previous advice. Old beliefs have been overturned and new research avenues opened. Some controversies have heated up. Things are moving fast. In case you missed something, *Cardiac Consult* shares this roundup of the latest developments in our understanding of diet and heart disease.

FAT

Evidence remains robust that elevated serum cholesterol, specifically LDL cholesterol, is a strong predictor of coronary artery disease in patients of all types and ages.

Reducing LDL cholesterol remains a primary goal of preventive treatment for coronary artery disease. Trans and saturated fats are known to raise levels of LDL cholesterol in the blood. The questions are: *How much?* and *Is it significant?*

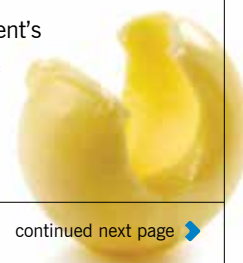
Butter, Beef and Bacon

Recent well-regarded studies suggest that the answers to these questions are much more nuanced than previously thought. Yet for over 50 years, patients have been counseled to avoid butter, whole milk and cream as well as beef, bacon and other meats based on their high saturated fat content. Steven Nissen, MD, Chair of Cardiovascular Medicine at

Cleveland Clinic, is often asked by the media to explain this apparent reversal of medical opinion.

"High cholesterol is a metabolic condition that can only be moderately influenced by diet," says Dr. Nissen. "Most circulating cholesterol is produced by the liver. Dietary cholesterol accounts for only about 15 to 20 percent of serum cholesterol. Changing the diet typically has only a modest effect on serum cholesterol levels."

Indeed, the above-cited report of the government's advisory committee concludes that "available evidence shows no appreciable relationship between consumption of dietary cholesterol and serum (blood) cholesterol."



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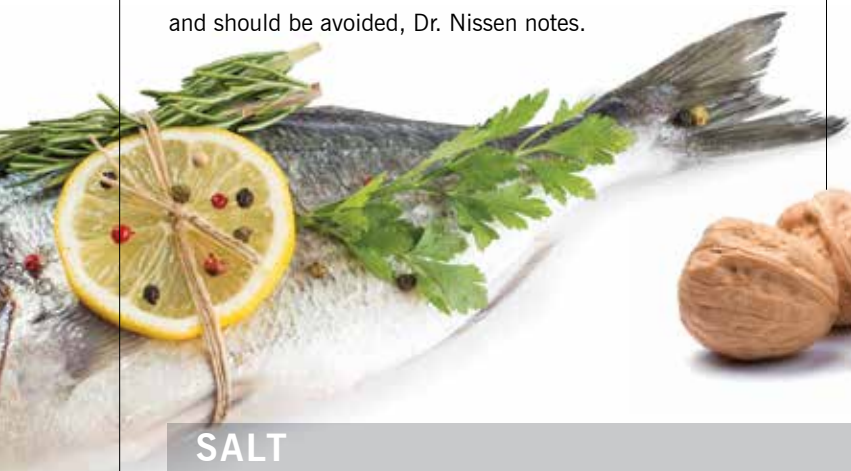


Fat Bans Spur Unhealthy Substitutions

Dr. Nissen believes previous recommendations against saturated fats contributed to the current epidemics of obesity and diabetes by promoting substitution of foods that are high in trans fats, simple sugars and carbohydrates.

"If you use a bit of butter to flavor your cooking, it's not a sin," he says. Moderation is the key to consuming fat. "There are a lot of reasons to hedge one's bets, but you don't have to absolutely avoid saturated fats. You just want to keep them under control."

Trans fats, also known as hydrogenated vegetable oil, are consistently linked to an increased risk of heart disease and should be avoided, Dr. Nissen notes.



Go Mediterranean

What went wrong? "High-quality research requires meticulous methodology of the sort that's evolved only recently with development of the randomized controlled trial," says Dr. Nissen. "Research before the modern era relied mostly on observational studies, with all their inherent biases."

One study that Dr. Nissen strongly endorses is the PREDIMED investigation, published in the *New England Journal of Medicine* in 2013. Looking at a high-risk population of 7,500 people, it found that a Mediterranean diet including extra virgin olive oil or nuts reduced the incidence of major cardiovascular events. "This is a high-quality study that blows the low-fat diet myth out of the water," he says. "It's good news for people advocating a sensible, balanced and tasty diet. Eat a Mediterranean diet, live long and enjoy life!"

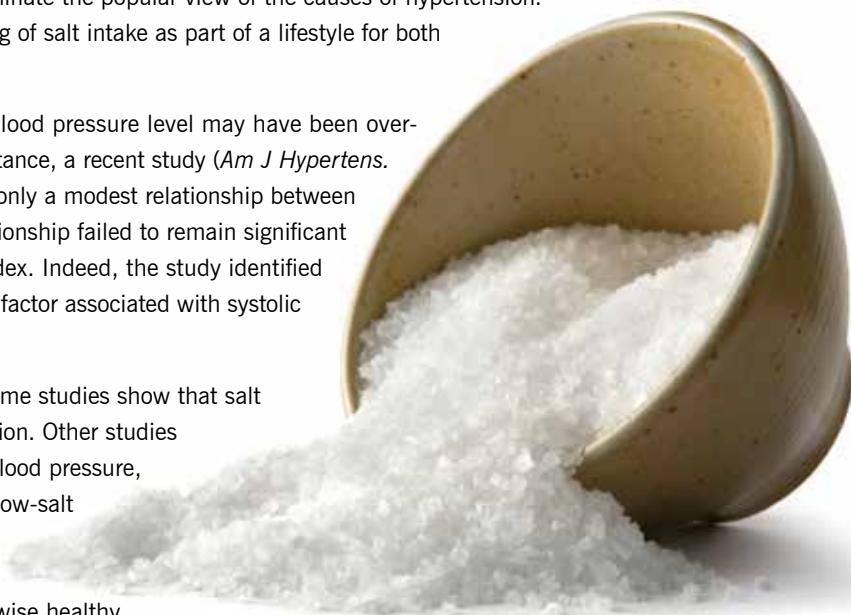


SALT

In the mid-20th century, Cleveland Clinic researcher Irvine Page, MD, bucked the tide of contemporary opinion about hypertension and proposed what he called the mosaic theory, which postulated that hypertension resulted from a variety of factors, including heredity, environment, hormones and diet. Since Dr. Page's time, diet — particularly dietary sodium — has come to dominate the popular view of the causes of hypertension. Virtually all dietary guidelines now recommend lowering of salt intake as part of a lifestyle for both prevention and control of hypertension.

Some new research, however, suggests salt's role in blood pressure level may have been over-emphasized, at least for the general population. For instance, a recent study (*Am J Hypertens.* 2015;28:362-371) of more than 8,000 adults found only a modest relationship between salt intake and systolic blood pressure — and the relationship failed to remain significant after accounting for factors like age and body mass index. Indeed, the study identified body mass index as the most important modifiable risk factor associated with systolic blood pressure.

"The science here is pretty murky," says Dr. Nissen. "Some studies show that salt intake is linked to heart disease, particularly hypertension. Other studies are not so clear. We tell people that if they have high blood pressure, they should probably try to reduce salt in their diet. A low-salt diet high in fruits and vegetables does seem to lower blood pressure and might keep them off medication. If an individual doesn't have hypertension and is otherwise healthy, reducing salt is not so much of a priority. You don't want to overdose on salt, but it may not be as big a problem as the public has been led to believe."





RED MEAT AND EGGS

For decades, eggs and red meat have topped the list of foods implicated in cardiovascular disease because of their high levels of dietary cholesterol. But the new science-led exoneration of fat described earlier in this article would seem to let red meat and eggs off the hook. And it largely has, at least when it comes to fat. But a whole new line of investigation focused on intestinal bacteria is keeping eggs and red meat in the spotlight.

Going for the Gut

Stanley Hazen, MD, PhD, Cleveland Clinic's Section Head of Preventive Cardiology and Rehabilitation, has published one study after another linking the metabolic product of bacterial digestion of substances found in red meat and egg yolks with development of pathologies ranging from atherosclerotic plaque to heart failure to chronic kidney disease. (These studies, published in the *New England Journal of Medicine* and other top journals, were detailed in the Winter 2015 *Cardiac Consult*.) According to Dr. Hazen's studies, increased blood levels of a compound formed by gut microbes following consumption of foods like red meat and egg yolks are associated with increased risk of adverse cardiovascular outcomes, including death, even when controlling for other risk factors and standard blood test results.

Briefly, here's how it works: Red meat and eggs (plus some dietary supplements and energy drinks) contain choline and carnitine, which gut bacteria metabolize into TMA (trimethylamine). TMA travels to the liver, where it is converted to TMAO (trimethylamine-*N*-oxide) and released into the bloodstream. There, TMAO becomes a factor that promotes vascular inflammation and formation of unstable plaques in arterial walls. The influence of TMAO on cardiovascular disease is significant enough to have prompted Dr. Hazen to develop an assay to assess cardiac risk by measuring plasma TMAO.

Still Eat Meat?

So what are the dietary implications of these findings? When Dr. Hazen did a study comparing 51 habitual meat eaters with 26 vegetarians or vegans (*Nat Med.* 2013;19:576-585), he found that the vegetarians and vegans had much lower concentrations of plasma TMAO than did the meat eaters.

But recommendations must await further studies. "While multiple studies with thousands of subjects show high TMAO levels to be predictive of future cardiovascular events, no trials have yet directly tested whether lowering TMAO reduces cardiac risk," Dr. Hazen explains.

For now, he recommends moderation. "Current evidence suggests that people who eat a lot of red meat should consider cutting back," he says, noting that the same goes for eggs.



BACK TO THE FUTURE?

In the 1973 movie *Sleeper*, Woody Allen plays a health food store owner who awakens from suspended animation into a future world where scientists have reversed the current wisdom and now consider deep-fried foods, steak, cream pies and hot fudge to be the real health foods. The joke always gets a big laugh. But we have moved somewhat in that direction, at least where fat is concerned.



One thing we know for certain is that dietary recommendations will continue to be fine-tuned as scientists continue to study food's complicated effects on health. ■

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Tear out the related infographic brochure in this page spread and share it with a patient today. Refer patients to the infographic online at clevelandclinic.org/dietandheart.



Public Reporting of Cardiovascular Outcomes:

How Well Do You *Really* Understand It?

National-level public reporting of clinical outcomes in cardiovascular care began in 2011 with voluntary reporting of metrics from the Society of Thoracic Surgeons' (STS) Adult Cardiac Surgery Database. As healthcare shifts toward ever-greater transparency, new public reporting initiatives are proliferating. The editors of *Cardiac Consult* thought the time was right for a primer on this fast-evolving area.

Q: What constitutes “publicly reported data”?

A: Less than you may think. Only audited clinical registry data contain the granularity needed to provide the meaningful information that payers, policymakers and patients increasingly demand. Such data typically include metrics for outcomes, structure and process, and they allow for risk adjustment to enable fair evaluation according to severity of patient mix.

In contrast, outcomes reports based on administrative data lack the critical clinical information about patients to provide truly credible, relevant information. As a result, these types of reports are not considered publicly reported data by key stakeholders.

Though several U.S. states have long mandated reporting of selected cardiac surgery outcomes, the only clinical registry data on cardiovascular practice that have been publicly reported at the national level in recent years are from two STS databases: the Adult Cardiac Surgery Database and the Congenital Heart Surgery Database. But new initiatives for national-level public reporting of more clinical registry data are in the works (see final question).

Q: Who participates in voluntary public reporting of clinical registry data?

A: Whoever chooses to. Public reporting from the STS registries (and soon-to-come reporting from American College of Cardiology [ACC] registries — see below) is voluntary. While the STS reports that over 90 percent of U.S. adult cardiac surgery centers participate in STS registries, not all of them voluntarily report their data.

For instance, Cleveland Clinic was the only one of the top 10 U.S. heart programs (according to *U.S. News & World Report*, 2014-15) with publicly reported data in all three categories of the STS Adult Cardiac Surgery Database for the July 2013-June 2014 reporting period. The other programs either did not publicly report or did not have sufficient CABG + AVR volume to be granted a rating in that category.

Q: What drives public reporting, and what are its implications?

A: The central rationale for public reporting is to provide transparency and accountability in outcomes to inform decision-making by patients, payers and policymakers. With greater demand for transparency, public reporting of outcomes should help build public trust and may encourage adoption of best practices. While the public benefits from these effects of public reporting, it shouldn't lose sight of the risk of unintended consequences, including potential inducements toward risk aversion in patient selection (i.e., cherry-picking).

Q: What's next in public reporting?

A: Various developments are underway or on the horizon:

- The STS now offers voluntary public reporting from its General Thoracic Surgery Database and later this year will introduce ratings and public reporting for mitral valve replacement and repair procedures.
- Later this year the ACC will begin offering participants in its CathPCI Registry and ICD Registry the option to take part in public reporting of selected metrics from these registries.
- Insurers and other payers are increasingly factoring clinical registry data into contracts with health systems, making reimbursement levels dependent on selected quality metrics.
- Public reporting of physician-specific outcomes is under active discussion by some groups and may soon become a reality.

“Public reporting is here to stay,” says Joseph Sabik, MD, Cleveland Clinic's Chairman of Thoracic and Cardiovascular Surgery. “Cleveland Clinic is proud to be in the forefront of this movement.” ■

★★★ Public Reporting Snapshot ★★★

Cleveland Clinic is among only 1 percent of U.S. hospitals to achieve a three-star (highest) rating in all three reportable categories of the STS Adult Cardiac Surgery Database for Jan.-Dec. 2014:

- CABG Composite Quality Rating (9.4% of hospitals achieved)
- AVR Composite Quality Rating (7.8% of hospitals achieved)
- CABG + AVR Composite Quality Rating (7.5% of hospitals achieved)

The ratings are based on combined registry data for Cleveland Clinic's main campus and its Fairview and Hillcrest regional hospitals.



Decompression Surgery for Thoracic Outlet Syndrome:

When, How and in Whom This Singular Specialty Procedure Is Warranted

By Rebecca L. Kelso, MD

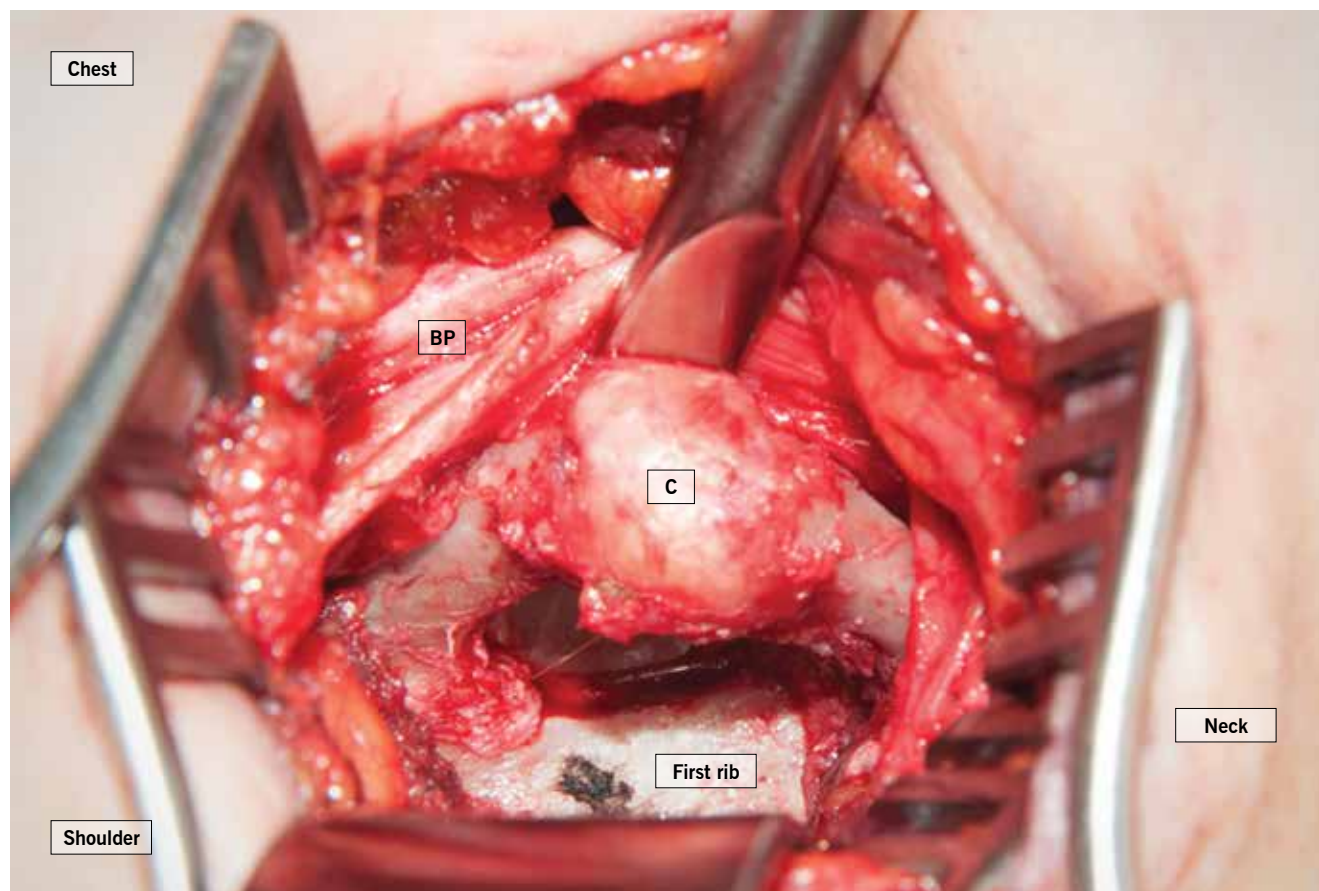


Figure 1. Retraction of the brachial plexus (BP) in the case patient showing the cervical rib (C) and articulating joint. Note the first rib more posteriorly.

Case Presentation

A 53-year-old right-handed man presents to Cleveland Clinic's Department of Vascular Surgery for a consult evaluation for thoracic outlet syndrome (TOS) (see box). He has a history of chronic upper back pain (> 4 years), neck pain (> 3 years), and left arm pain and discomfort (3 years). Because his symptoms improve with his left arm at rest, he avoids using it as much as possible and has had resultant muscle wasting. He complains of burning, stabbing, throbbing pain in the left armpit that travels down to the fourth and fifth fingers, and in the proximal left palm. He reports having intermittent numbness in his left arm, hand and fingers since childhood, along with muscle wasting in his left hand.

TOS in brief

Thoracic outlet syndrome (TOS) involves upper extremity symptoms due to compression of the neurovascular bundle at the superior thoracic outlet by any of various structures in the area just above the first rib and behind the clavicle. Among the three TOS subtypes — neurogenic, venous and arterial — neurogenic accounts for about 96 percent of cases, followed by venous (3 percent) and arterial (1 percent).

continued next page ➔

The patient reports that doing overhead work for prolonged periods is an exacerbating factor. As an inspector at a steel company, he repeatedly picks up 2 to 10 pounds daily — a task for which he uses his right arm. He avoids using his left arm for any prolonged activity above shoulder level (e.g., holding the telephone to his ear, hair-washing, holding the top of the steering wheel).

The patient has undergone physical therapy and taken pain medications, without marked relief. He reports that recent lidocaine injections to his cervical neck were helpful.

He has undergone orthopaedic and neurologic evaluation. Previous diagnostic testing included a spinal X-ray, MRIs of the spine and shoulder, and electromyography testing. Of note, he was found during workup to have a full left C7 cervical rib, a rare anatomic variation. While 0.75 percent of the population has a complete or incomplete cervical rib, many have only an extra length, whereas this patient has a full rib with an articulating joint in the middle.

Diagnosis and Management Plan

When a cervical rib is present along with signs and symptoms of TOS, it is most commonly a case of neurogenic TOS, which was my diagnosis for this patient. While no one test or

physical finding can definitively diagnose TOS, I based this diagnosis on the clinical history, physical exam findings and elimination of other diagnoses.

I recommended the clear course of action — decompression surgery to remove the cervical rib — to which the patient agreed. The surgical approach can be supraclavicular or transaxillary and is decided at the surgeon's discretion based on technical experience, presence/absence of a cervical rib, involvement of the upper brachial plexus cords and the patient's surgical history.

The Surgical Approach

This neurogenic case called for a supraclavicular approach, due to the presence of the cervical rib. If the surgery had been for venous TOS or a milder neurogenic case, I would have used a transaxillary approach.

Under a supraclavicular approach like this, a neck roll is used to extend the shoulders and the head is rotated to the contralateral side. An incision is made above the clavicle in a parallel fashion from the lateral head of the sternocleidomastoid toward the shoulder. The platysma is transected and tissues dissected to identify the scalene fat pad. The fat pad should be mobilized in a superior lateral fashion, with care taken to protect the thoracic duct. This allows exposure of the anterior scalene muscle. The phrenic nerve will be seen from superior lateral to inferior medial and should be dissected and protected.

The anterior scalene is partially resected, allowing visualization of the subclavian artery, which can be mobilized to improve exposure of the rib. The brachial plexus will be seen lateral to the artery and should be dissected from the surrounding tissue. The first rib will lie underneath these structures and can be manually palpated. The cervical rib lies more superiorly, and with retraction of structures, it can be cleared circumferentially from its posterior attachment (Figure 1). The rib or ribs are then removed en bloc (Figures 2 and 3).

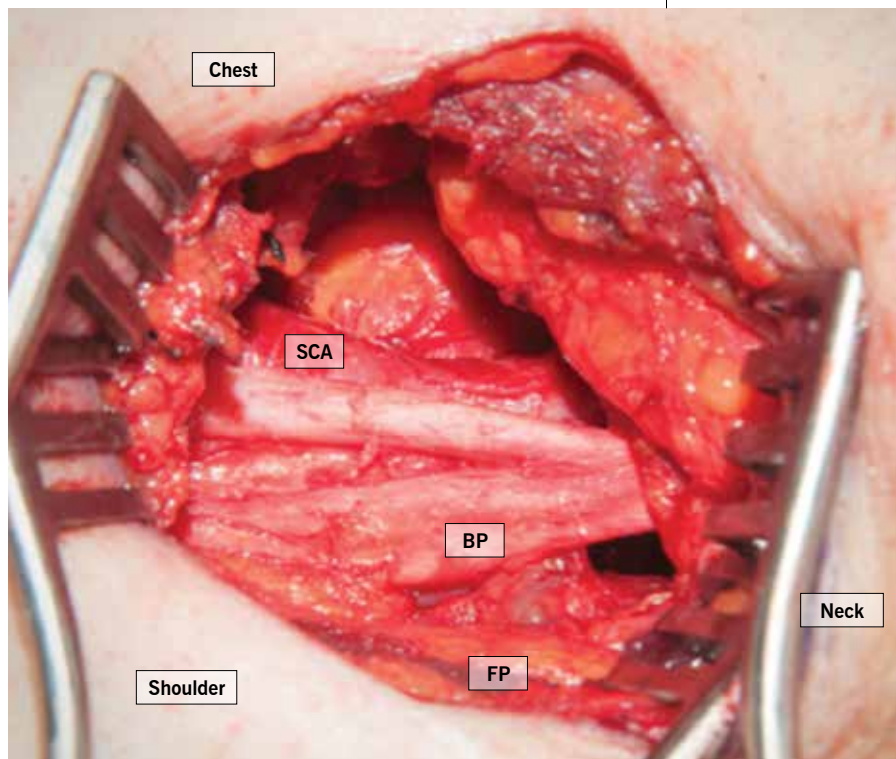


Figure 2. The brachial plexus (BP) back in normal position after resection of the cervical rib and first rib with associated scalene muscle attachments. (SCA = subclavian artery; FP = fat pad)

Many patients have TOS symptoms for too long – nine to 18 months or more – before referral.

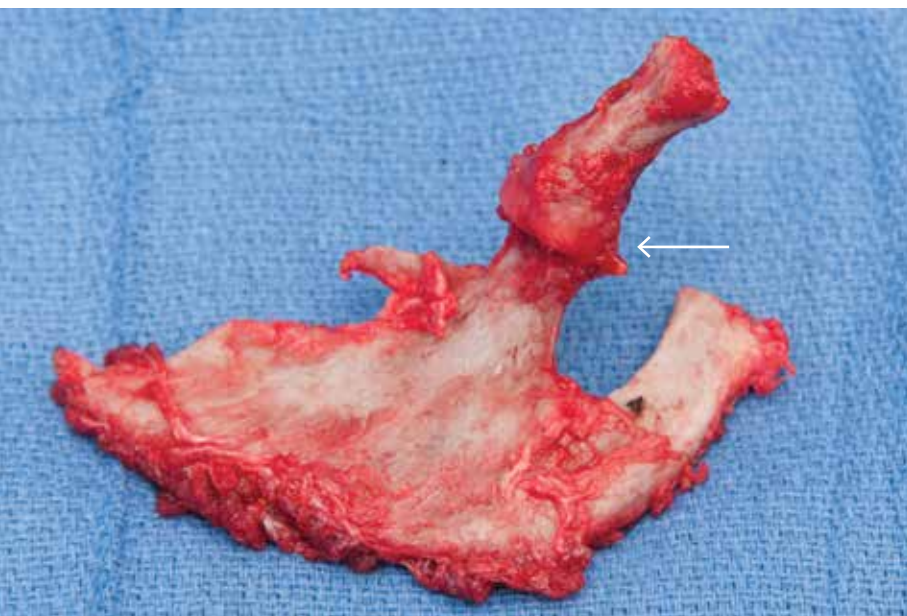


Figure 3. En bloc resection of first rib and attached cervical rib. Arrow notes articulation joint in the cervical rib.

The postoperative course includes a 24-hour observation period, with a combination of NSAIDs and narcotics for pain control. We require postoperative physical therapy for all surgery patients.

Case Update

The patient is now one month postop and showing improvements, including in all ulnar-based symptoms. His shoulder pain has improved, pain has decreased in his neck with the movement of his head and he is now starting physical therapy. Because of the severity of his preoperative symptoms, he will likely have a prolonged recovery (two to three months) with nerve recovery continuing for six to 12 months.

TOS: An Uncommon but Important Specialty Focus

While TOS is a fairly unusual specialty area within vascular surgery, it's an important one — and one in which several Cleveland Clinic vascular surgeons have extensive experience. My own caseload has grown to approximately 30 TOS surgeries per year, with a mix of neurogenic and venous cases. Because these procedures can affect arm function, TOS cases tend to be highly litigious, which makes surgeon skill even more important.

Many patients referred to our center have had symptoms for nine to 18 months or more, seen various specialists and undergone multiple diagnostic tests, many of them unremarkable. Because of this widespread delay in diagnosis and the lack of confirmatory tests — as well as the fact that earlier interventions tend to be most successful — we urge colleagues to refer whenever there is a suspicion for TOS.

Special attention to the history and symptoms is crucial to diagnosis of TOS. Symptoms often overlap with more common diagnoses, including cervical spine disorders, rotator cuff or shoulder injury, ulnar nerve entrapment and carpal tunnel syndrome. These diagnoses must be excluded, often through neurologic and orthopaedic evaluations.

Diagnosing arterial and venous TOS is sometimes easier than diagnosing neurogenic disease, due to arm findings related to chronic injury to vessels. However, patients with extensive and prolonged symptoms of neurogenic TOS may have an element of sympathetic nerve involvement with color changes, swelling and mottling, which can be confused with arterial or venous TOS.

Surgery for TOS: When Needed, Usually a Success

Only 20 to 30 percent of patients with TOS need surgical treatment, so evaluation includes careful consideration of whether surgery will benefit the patient. Surgery primarily involves resection of the rib(s) and associated scalene muscles and release of scar tissue surrounding the neurovascular bundle. Patients with a cervical rib (like this one) often require surgical treatment, though many other neurogenic patients achieve satisfactory relief from TOS-specific physical therapy and medical management. Since most cases of venous or arterial TOS present with symptoms, surgery is first-line therapy in these patients.

Surgical outcomes are generally positive for well-selected patients. With judicious patient selection and proper patient adherence to physical therapy and movement restrictions until pain is resolved, surgical treatment of TOS can lead to improvement in about 80 percent of patients. ■

Contact Dr. Kelso, a surgeon in the Department of Vascular Surgery, at kelsor@ccf.org or 216.445.3527.



Sizing Up the New Neprilysin Inhibitor for Chronic Heart Failure

If approved as expected, it's likely to supplant ACE inhibitors as standard therapy.

A novel drug for chronic heart failure (CHF) that recently outperformed the standard of care in the pivotal PARADIGM clinical trial is poised to become the treatment of choice in CHF patients who tolerate it. That's the take of Cleveland Clinic's Randall Starling, MD, MPH, assuming the agent gains FDA approval as expected this year.

The drug, known as LCZ696, "would have applicability to all patients with heart failure and a reduced ejection fraction (defined as < 40 percent) who have tolerated a standard dose of ACE inhibitor therapy," says Dr. Starling, Medical Director of Cleveland Clinic's Kaufman Center for Heart Failure. He served as U.S. leader of the PARADIGM steering committee. Cleveland Clinic was a participating center in the phase 3 trial, the results of which were published in the *New England Journal of Medicine* (2014;371:993-1004).

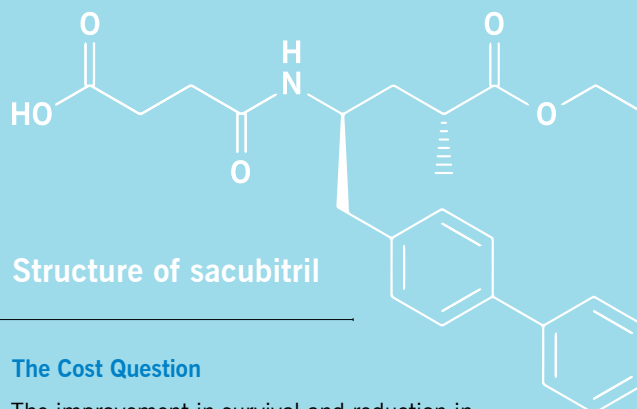
Combo Agent with a Novel Mechanism: Neprilysin Inhibition

LCZ696 is a combination of the angiotensin II receptor blocker valsartan and sacubitril. The latter compound (see structure above) is a neprilysin inhibitor prodrug that augments endogenous natriuretic peptides and other beneficial counterregulatory systems (i.e., bradykinin, adrenomedullin) in CHF.

Inhibiting neprilysin results in significant reductions in systemic vascular resistance, pulmonary artery pressure, pulmonary capillary wedge pressure and right arterial pressure in patients with CHF. Other effects include vasodilation, enhanced sodium and water excretion, and preservation of glomerular filtration.

Superior to ACE Inhibition in PARADIGM

These beneficial properties of neprilysin inhibition, when combined with valsartan, translated to a 20 percent relative reduction in the composite primary end point of death from cardiovascular causes and/or hospitalization for heart failure compared with the ACE inhibitor enalapril among the 8,442 patients with CHF and reduced ejection fraction enrolled in PARADIGM. Each of the components of this composite end point was reduced by about 20 percent in recipients of LCZ696 compared with enalapril, and greater symptomatic improvement was reported. LCZ696 also was associated with a 16 percent reduction in overall mortality relative to enalapril.



Structure of sacubitril

The Cost Question

The improvement in survival and reduction in CHF-related hospitalizations imply that LCZ696 has the potential to be a cost-effective therapy once available, depending on its price, according to Dr. Starling. "I think patients will want this drug and physicians will want to use it," he says. "But we need to see how it is priced and reimbursed to know whether there may be cost-related obstacles to access."

Careful Blood Pressure Screening Will Be Key

Because LCZ696 can cause hypotension, patients will require careful blood pressure screening before the drug can be considered, Dr. Starling notes. In PARADIGM, approximately 10 percent of patients had challenges maintaining blood pressure during the screening phase or after trial initiation. Screening involved two single-blind run-in phases — first with enalapril 10 mg twice daily and then, if no unacceptable side effects occurred, with LCZ696 (100 mg twice daily followed by 200 mg twice daily) — before randomization to enalapril at 10 mg twice daily or LCZ696 at 200 mg twice daily.

"The main message is that if a patient is tolerating a standard dose of an ACE inhibitor, he or she will probably tolerate LCZ696 just fine," Dr. Starling says. "You'll just want to keep a careful eye on the blood pressure."

Appropriate institution of LCZ696 in patients with CHF who have been treated with an angiotensin receptor blocker rather than an ACE inhibitor is uncertain, he notes, adding that eventual approval language from the FDA may give some guidance. "I'd anticipate there will be a role for this drug in that patient population although it has not yet been specifically tested." ■

Contact Dr. Starling at starlir@ccf.org or 216.444.2268.



Collaborating with MedStar for Integrated, Centralized Cardiac Registry Information Flow

This is the first in a new series of profiles of how Cleveland Clinic's Miller Family Heart & Vascular Institute works with allied and affiliated provider organizations around the nation to help them improve a specific aspect of their clinical or operational functions. For more on the Heart & Vascular Institute's advisory services, visit affiliatenetwork.clevelandclinic.org.

Context and Challenge

Cleveland Clinic's Miller Family Heart & Vascular Institute formed a clinical and research alliance in early 2013 with MedStar Heart & Vascular Institute, which serves a large population in the Maryland and Washington, D.C., region.

At the time, MedStar's registry data collection process benefited from experienced cardiac surgery data abstractors and a solid IT infrastructure. However, there were multiple opportunities to align and integrate its two major repositories of registry information — for cardiac surgery and interventional cardiology — to provide more efficient, timely, accurate, validated, actionable and personal information to the clinical teams for quality process improvement.

To meet these challenges, MedStar leadership enlisted Cleveland Clinic's support to create an integrated and centralized cardiovascular registry and quality process to accurately collect, validate, analyze and communicate results across the clinical disciplines and engage physicians in quality improvement initiatives. The broader aim was to provide a base for programmatic improvement and allow the health system to publish quality and outcome metrics to demonstrate overall service capabilities and value.

Approach and Solutions

Beginning with its Washington Hospital Center, MedStar implemented the specific changes outlined below. At every step, its efforts were guided by administrative and clinical advisors from Cleveland Clinic, who shared processes and insights from their own experience with similar initiatives at Cleveland Clinic.

- **Developed an integrated cardiovascular service line registry and quality dashboard.** After multiple iterations, an integrated cardiovascular service line quality dashboard has been produced and is reviewed on a routine basis. The dashboard includes specified core measures, patient safety indicators, readmission and mortality measures, and executive summary metrics from the national registry reports for cardiac surgery, percutaneous coronary intervention (PCI) procedures and implantable cardioverter-defibrillator procedures.
- **Began integration of registry and quality personnel** into a centralized structure to optimize and standardize data collection, validation, analysis and communication and to enable improved cost management. This centralization of structure and processes promotes physician and staff engagement and aligns with cardiovascular service line quality goals.
- **Began holding quality meetings** with a multidisciplinary team from both MedStar and Cleveland Clinic. Discussions revolve around metric results review, the strategic priority of specific metrics and process changes to improve metrics.

Outcomes and Observations

MedStar has seen some early successes in the wake of these changes (see sidebar, next page), including a substantial decline in risk-adjusted mortality after aortic valve replacement (Figure 1) and a marked increase in use of the radial artery for

continued next page ➤



Figure 1.

Mortality for Aortic Valve Replacement Surgery

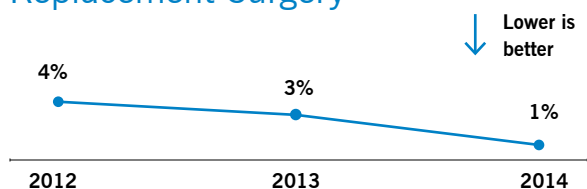
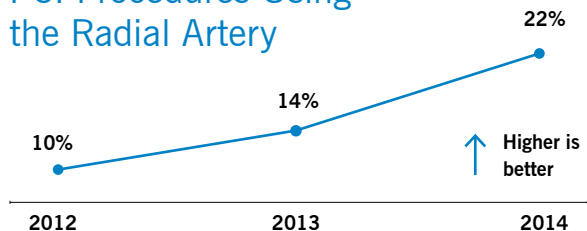


Figure 2.

PCI Procedures Using the Radial Artery



PCI procedures (Figure 2), which decreases bleeding complications, reduces length of stay and increases patient satisfaction.

“Partnering with Cleveland Clinic has given us the opportunity to focus our physicians and staff on fostering a transparent, outcomes-based environment while also allowing us to benchmark ourselves against the best heart program in the world,” says Allen Taylor, MD, Chief, Division of Cardiology, MedStar Heart & Vascular Institute. “To help us get there, they shared best practices around implementation of a high-quality data and informatics program, which enabled us to obtain clean data that we could act on. And the ongoing collaboration on developing a pathway to performance transformation provides tremendous value to our organization.” ■

Selected Outcomes of the Initiative

- An integrated quality dashboard that aligns across MedStar’s cardiovascular service line
- Newly instituted interdisciplinary quality meetings involving staff from the Heart & Vascular Institutes of both MedStar and Cleveland Clinic
- Progress toward reorganizing quality and registry personnel into a centralized, integrated and aligned structure across the cardiovascular service line
- Quality and registry outcomes showing improvement across cardiovascular service line (see graphs above)

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Information/registration: ccfcme.org/CardioReview

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Oct. 30, 2015

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In co-providership with MedStar
Heart & Vascular Institute

Information/registration: ccfcme.org/CVDDC

Contemporary Management of Cardiovascular Disease

Nov. 20-21, 2015

Anatole Hilton, Dallas, Texas

In co-providership with Baylor Scott & White Health

Information/registration: ccfcme.org/CVDTX

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March 4-6, 2016

Eden Roc Hotel, Miami Beach, Fla.

Information/registration: ccfcme.org/echo





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Outcomes Data

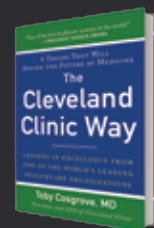
View Outcomes books at clevelandclinic.org/outcomes.

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Learn about our Executive Visitors' Program and two-week Samson Global Leadership Academy immersion program at clevelandclinic.org/executiveeducation.



The Cleveland Clinic Way

By Toby Cosgrove, MD, CEO and President, Cleveland Clinic

Great things happen when a medical center puts patients first. Visit clevelandclinic.org/ClevelandClinicWay for details or to order a copy.

About Cleveland Clinic

Cleveland Clinic is an integrated healthcare delivery system with local, national and international reach. At Cleveland Clinic, more than 3,200 physicians and researchers represent 120 medical specialties and subspecialties. We are a main campus, more than 80 northern Ohio outpatient locations (including 16 full-service family health centers), Cleveland Clinic Florida, Cleveland Clinic Lou Ruvo Center for Brain Health in Las Vegas, Cleveland Clinic Canada, Sheikh Khalifa Medical City and Cleveland Clinic Abu Dhabi.

In 2014, Cleveland Clinic was ranked one of America's top four hospitals in *U.S. News & World Report's* "Best Hospitals" survey. The survey ranks Cleveland Clinic among the nation's top 10 hospitals in 13 specialty areas, and the top hospital in heart care (for the 20th consecutive year) and urologic care.

Cardiac Consult



Dr. Rakesh M. Suri Joins Cleveland Clinic's Heart & Vascular Institute

Will lead Medical Operations at Cleveland Clinic Abu Dhabi

Cleveland Clinic is pleased to announce that cardiothoracic surgeon Rakesh M. Suri, MD, DPhil, has joined the staff of Cleveland Clinic. He will begin his tenure as Chief of Thoracic and Cardiovascular Surgery and Chief of Medical Operations at Cleveland Clinic Abu Dhabi. The new 4.4 million-square-foot specialized medical center in the United Arab Emirates began treating patients earlier this year.

Dr. Suri will also maintain a presence at Cleveland Clinic's main campus, where he will return several times a year to perform heart surgeries and serve as Professor of Surgery at Cleveland Clinic Lerner College of Medicine.

He is among the world's most experienced practitioners of robotic-assisted heart surgeries and has helped pioneer the use of minimally invasive platforms in valve repair procedures. His diverse clinical and research interests include mitral and aortic valve repair, robotic and minimally invasive cardiac surgery, reoperative cardiac surgery and the pathobiology of myxomatous mitral valve disease, among many others.

"Dr. Suri is a gifted and talented young surgeon who is rapidly developing a world-wide reputation for valve surgery, particularly robotic mitral valve surgery," says Lars Svensson, MD, PhD, Chairman of the Sydell and Arnold Miller Family Heart & Vascular Institute. "We are delighted he has joined our very strong heart surgery team and is helping our seminal program in Abu Dhabi grow into a premier place for patients to receive world-class care in the Cleveland Clinic tradition."

Dr. Suri comes to Cleveland Clinic from Mayo Clinic, where he served as a consultant in the Division of Cardiovascular Surgery, Professor of Surgery, and Chair of the Enterprise Robotic Practice, among other education- and innovation-oriented roles. He completed residencies at Mayo Clinic and the University of Toronto, where he received his medical degree, and completed doctoral studies at Oxford University in the U.K. as a Rhodes scholar.

In addition to lecturing extensively around the world, Dr. Suri has led, or collaborated on, several FDA multicenter trials, contributed to more than 230 journal articles and book chapters, and been granted 11 patents. ■