

CARDIOVASCULAR CENTER TRIAL 'PIVOTAL' TO MINIMALLY-INVASIVE REPLACEMENT OF AORTIC VALVES — AND THE FUTURE OF HEALTH CARE

A TEAM TO THE CORE



It's a bold statement Stanley Chetcuti, M.D., makes without hesitation: "CoreValve is forcing us to change the way we take care of patients."

Chetcuti is one of the principal investigators for the University of Michigan Cardiovascular Center's section of the Medtronic CoreValve U.S. Pivotal Trial, which has been testing the effectiveness of a minimally invasive alternative to open-heart surgery in relieving severe aortic stenosis, a condition where the aortic valve narrows, limiting blood flow from the aorta to the rest of the body.

His observation isn't only about the device itself. The prognosis for a successful outcome was pretty rosy anyway, given the CVC's distinguished track record in research and treatment. And both the CoreValve and the Edwards SAPIEN transcatheter heart valve, a similar implant that was approved by the FDA in November, have been used extensively and to good effect worldwide but had not been evaluated in American trials on American patients.



Chetcuti's comment also refers to more than transcatheter aortic valve implantation, or TAVI, the percutaneous procedure used to place new valves in aged patients with complications that make open-heart surgery too risky — which is the case with about a third of the 100,000 Americans diagnosed with the ailment every year.

Giving them a chance they wouldn't otherwise have at a better life, if not necessarily a longer one, is undeniably important, but the means by which that chance is achieved is what has global significance for the future of medicine itself. CoreValve, as used above, is shorthand for the entire process.

"It begins to open our minds to how medicine needs to evolve in the next 10 to 15 years," says Chetcuti, an interventional cardiologist who is the Eric J. Topol Collegiate Professor of Cardiovascular Medicine and associate professor of internal medicine. "That's the fundamental issue — not taking care of people with stenosis, but how we train our young doctors, how we use technology. The way we do incisions, the way we do surgery, the way we share data are all going to explode in the next five to 10 years."

The trial provides a snapshot of the patients of the future and how medicine will have to adapt in order to treat them.



Stanley Chetcuti

Typically in their 80s or 90s, and suffering from a variety of additional ailments, they present in the same way many baby boomers will present in the not-too-distant future, and treating them will require exactly what the success of the CoreValve trial required: teamwork, technology, and a therapeutic culture that treats the whole person.

"Medicine is much more complex now than it was 20 to 30 years ago," says Himanshu J. Patel, M.D., an associate professor of surgery and another principal investigator. "It's logical to assume at this point that to deliver very high-end care, one person can't do it. Outcomes are much better if there is a group of individuals that is looking at how to go about treating patients who are complicated from the outset. What this collaborative group does is bring different perspectives to the patient, different talents and different ideas, and allows us to come up with better ways to treat them."

The leadership of the team reflects this philosophy. Chetcuti and P. Michael Grossman, M.D., are the principal interventional cardiology investigators, and there are two principal surgical investigators as well: G. Michael Deeb, M.D., and Patel. In addition to surgeons and interventional cardiologists, the team includes anesthesiologists, radiologists, interventional radiologists, intensivists, neurologists, echocardiographers, physician assistants and nurses.

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Himanshu Patel

An avid soccer fan who also played water polo in his native Malta, Chetcuti draws many lessons from sports. “You could be a star quarterback but unless your linemen are strong and protect you, you’re no good,” he says. “What sports teach you is to have respect for every team member. The four physicians are the ones who get the glory, but there are more than 80 people working on this project. Everyone does a bang-up job and it’s critical to success.”

Here’s another lesson from the athletic realm. “No matter how good you are, you can’t just go play the game,” he says. “A team becomes a work of art due to the extreme hard work that it does on the practice field. To be successful with CoreValve has taken that kind of dedication — hours and hours of drills and preparation.”

The team has dry runs with dummy patients, practices on simulators, and creates scenarios where, for example, a complication arises and everyone figures out his or her role.

“Our procedure room is very much like a Formula One pit crew, where if something goes wrong it can be fixed very quickly because everyone is trained,” says Chetcuti. “You see these guys change a tire in 60 seconds, that’s how these people are trained. The concept of a care team may have been a nice cliché a few years ago, but with CoreValve you have to

put your concept into practice, and we’ve been able to do it extremely well. I know I can rely on the person next to me.”

As the interventional fellowship director for the last six years, Chetcuti is also concerned about the fit between training and practice, a place where CoreValve’s technological emphasis has been a boon. “The truth is that many physicians are in their 40s and 50s, and people in their 20s and 30s have grown up in the computer age,” he says. Their instructors are well advised to not only be comfortable with this orientation but also nurture its therapeutic applications.

TEAMWORK AND TECHNOLOGY

In many ways, technology’s role in Patel’s career illustrates the future of medicine as well as the patients in the trial do. He vividly remembers following the saga of Barney Clark’s historic artificial heart implant on television as a boy in Johnstown, Pennsylvania, and “thinking that was pretty cool. After that, I wanted to do heart surgery.”

By the mid 1990s, when he was a general surgery resident at the University of Rochester, endovascular surgery had appeared on the scene. “I found that very intriguing,” Patel says. By 2005, he had joined the U-M faculty after being a thoracic surgery resident and clinical fellow in cardiac surgery here, and endovascular surgery was more than intriguing.

“We knew that more and more patients were going to be treated with endovascular means and that percutaneous valves were just around the corner,” says Patel. “I went off for three months on a sabbatical at the Cleveland Clinic and acquired a set of endovascular skills, so we would have that option for patients here at the U-M.”

He also acquired, or perhaps reinforced, a less tangible skill. “There were a lot of people there that I had done general surgery with in Rochester who were rapidly evolving endovascular technology,” he says. “That allowed me to work very, very closely with colleagues in different disciplines, which has become something I really enjoy.”

His main interest had long been treating diseases of the aortic valve and the aorta, but that had usually meant aneurisms. Stenosis, he says, was “a whole other thing,” and it broadened his comprehension of the *why* of surgery, as well as the *how*.

“Patients with aneurisms generally don’t feel bad; it’s just growing inside them and could decrease their life expectancy,”



P. Michael Grossman

says Patel. “We have to make them understand we’re not doing it to make them feel better but to make them live longer. When patients get older, at least in my experience, making them feel better is generally a more important goal than making them live longer. The approach you take is not just what their valve looks like but what the whole person looks like.”

Dialog informs that approach, Patel says. “If a patient tells me they want to get to their granddaughter’s graduation two years from now, that’s the goal. If they say they’re just sick and tired of being in the hospital, getting them home is the goal. That’s much different than someone who’s 45 and has valve disease and three kids to put through college.”

“Most of these valves are being placed in patients whose life expectancy after valve replacement may not be 20 years,” says Grossman, who is a clinical associate professor of internal medicine and directs the cardiac catheterization lab at the VA Ann Arbor Healthcare System. “The goals of these implantations, at least today, are to improve quality of life and only somewhat to improve quantity.”

“For the right patient, it is a life-transforming procedure,” says Chetcuti. “The key word is ‘right.’ That’s where we have to hone our diagnostic skills. Thirty percent of implanted patients still died within one year in the Edwards trial. It is our job to be able to identify those 30 percent before we put them

through the financial cost and the emotional burden of undergoing a procedure of little benefit. We have to avoid that.”

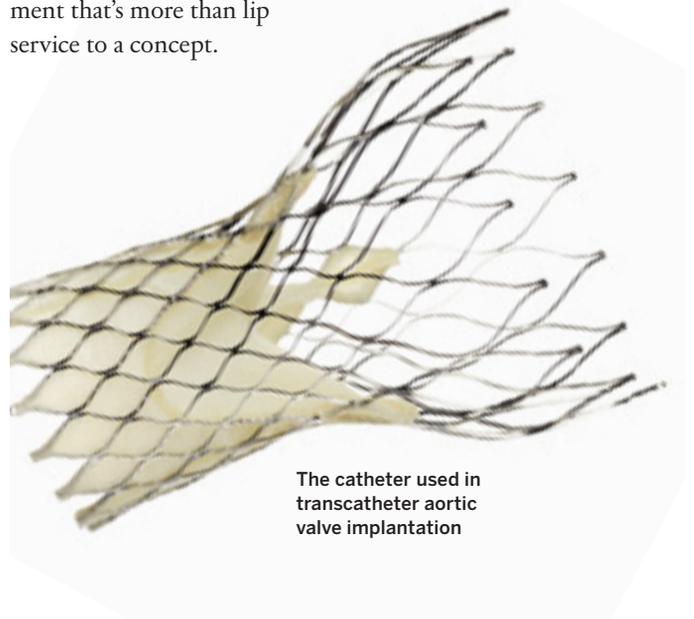
It’s a perspective he feels obliged to share with his students. “One of the things I try to pass on is that it’s important to step away from a procedure when it’s not appropriate,” he says. “When you’re doing something invasively, you have to make sure you’re doing it with the right intention of helping the patient feel better or live longer. One of the biggest problems in the field is people doing something just because they can.”

As significant as the CoreValve trial has been in a plethora of arenas, cross-pollination has also been at work. Michigan would never have been selected to participate in the first place if it hadn’t already demonstrated the kind of teamwork and expertise that boded well for success.

“The foundation of the team has been in place for many years,” says Grossman. “Because we work at one of the largest aortic and aortic valve surgical centers in the country, we’ve developed close relationships with cardiac surgeons who manage aortic valve disease. Out of a close working relationship and regular dialogue about patients and sharing of ideas, we’ve built a friendship and trust with each other. And I think the institution encourages this kind of collaboration, where we truly try to work as a team to take care of patients.”

“Even outside of the hospital, we’re friendly, so it makes things very easy at work,” says Patel. “With this group of patients, that’s a very important aspect of care.”

Such a level of collaboration, even camaraderie, doesn’t happen without consolidation, both organizational and physical, and such consolidation doesn’t happen without institutional commitment that’s more than lip service to a concept.



The catheter used in transcatheter aortic valve implantation

STEVE KUZMA

THERAPEUTIC CULTURE

The road to Michigan's pre-eminence in treating aortic problems can be reasonably said to have started more than a quarter of a century ago, when Deeb was recruited from Temple University, where he developed the heart transplant program, to direct U-M's Heart/Lung Transplant and Artificial Devices Program.

Consistent with Michigan's history of transcending boundaries to benefit patients, it soon became clear to him that a broader focus was in order. "We were seeing a lot of patients with difficult aortic problems that no one else wanted to handle," he says. "We started getting good results and publishing them, and our results were far superior to standard outcomes across the nation."

Deeb now heads the CVC's Multidisciplinary Aortic Clinic, which performs more than 500 surgical valve procedures a year, attracting people with aortic disorders from all over the country. Research has also prospered: CVC physicians and scientists have participated in more than 700 cardiovascular clinical trials in the past five years.

With the opening of the CVC building in 2007, all these resources were finally under one roof.



G. Michael Deeb

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"This building allows collaboration," Deeb says. "We're all taking care of the same patients and the same disease processes. Back in the old building, if I saw a patient and wanted a cardiologist or a vascular surgeon or an interventional radiologist involved, the patient would have to make an appointment and come back. Now, these people are right down the hall and can often see the patient immediately. It took a long time to get underway, but this is the way medicine should be."

If CoreValve is changing the way patients are cared for, it's by moving medicine further in directions the U-M was already pursuing. "This trial came at a time when we had all the right players in place, the right infrastructure, the right environment, the right ethos," says Chetcuti. "We were all prepared. This is proof of the concept that teamwork really does work in a medical environment."

"We've worked to set the standard for how a multidisciplinary team can and should take care of these patients," says Grossman. One of the payoffs is that University Hospital is the first in the state, and one of only three in the country, whose patients have access to both the Edwards valve and CoreValve.

They also have access to all-star caregivers who understand both why and how a team works. "For us," says Deeb, "every day is the Super Bowl, the seventh game of the World Series. We have to perform at that level every day." [M]