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**G. MICHAEL DEEB:** The aortic valve is the valve that sits between the left pumping chamber and the body. When the heart pumps blood out into the body, it pumps it through the aortic valve into the major blood vessel called the aorta. When a valve becomes stenotic, it begins to calcify, and so it takes more and more pressure to get the valve open.

And when that occurs, it causes an overload on the heart. And after a while, the heart begins to fail. And so when a patient develops severe aortic stenosis with heart failure and chest pain, that is when we consider aortic valve replacement.

**P. MICHAEL GROSSMAN:** The most common symptom of severely aortic stenosis is exertional shortness of breath, or shortness of breath when a patient tries to exercise, or even do activities of daily living. Most patients who come to us with severe symptomatic aortic stenosis really have an impaired quality of life, and are seeking a way to improve their quality of life. Well, a transcatheter aortic valve replacement or TAVR is a procedure where we use minimally invasive techniques to essentially replace a patient's aortic valve.

**G. MICHAEL DEEB:** We can do this predominantly with needle puncture, and we don't even need to make an incision. The most common area that we use are the femoral vessels down in the groin. And we use a needle and pass a guidewire up into the heart, and then pass the valve on a catheter over the wire into the aortic position, and then assess the valve, determine if we think that this is the ideal position, if there's any leak around the valve, or that the valve is opening and closing well. And if we don't believe that this is a perfect valve, then we can retrieve the valve and reposition it, and then slowly release it again.

**P. MICHAEL GROSSMAN:** Because TAVR is a minimally invasive procedure, the recovery time from the procedure itself is very short. And so patients recover from the procedure very quickly, and therefore can then begin the process of getting their strength back, of going through rehabilitation, and within a period of days to weeks, see significant or dramatic improvements in their quality of life.

**G. MICHAEL DEEB:** With a major open-heart surgery, the total recovery time is approximately three months. With the transcatheter valve replacement, the total time of recovery in an ambulating, high-risk, moderate-risk patient is about a week.

But they're ready to rock and roll. They don't want to be in the hospital. They want to go home.

They want to get back they want to get into life. And so it's very dramatic. This is one of the big a-ha moments in my life, was seeing the difference between a post-procedure transcatheter valve patient versus that of a surgical valve patient.

The University of Michigan has been a center of excellence for aortic valve pathology for many years. Our aortic valve surgery program has been the largest program in the state for approximately the last 10 years. And so we've been known, for many years, as an area of aortic excellence. We have a good history with a large experience, a good collaborative team-- not only the surgeon and cardiologist, the anesthesiologist, the echocardiographer, the nursing team, the physician assistants, and the technicians in the room. And so I think when the patient comes to the University of Michigan, they get the depth and breadth of a complete program.

The therapy has been under FDA trials. We initially began to perform this procedure in patients who were too sick to have open-heart surgery, and this form of therapy proved to be more effective than medical therapy. The new trial that's just beginning, the low-risk trial, patients have an option for transcatheter aortic valve, where they will be randomized one to one to transcatheter aortic valve and surgical aortic valve. We have valves that fit the majority of the patient population, and we feel that we can probably cover about 97% of the patient population with this valve range.

**STAN CHETCUTI:** We've worked hard to get in this position, to be able to offer our patients cutting edge technologies that may not be available on the market. So we are able to offer newer type of valves, or valve TAVR procedures in subsets of patients for whom it has not yet been offered for clinical use. For many, many years, the only viable option for our elderly patients was either a mechanical valve or a bioprosthetic valve.

The TAVR technology is an excellent form of therapy for the treatment of failed bioprosthetic valves. Most bioprosthetic valves usually last for about 10 to 15 years in a patient. So as you're getting into your 9th and 10th decade, it becomes a bit more cumbersome to expect to be able to have what we call a simple surgical valve replacement. With a minimally invasive route, we are able to place a TAVR valve in the old surgical valve and relieve any kind of valve dysfunction.

**P. MICHAEL GROSSMAN:** In the transcatheter aortic valve replacement, it's required and it is necessary that both an interventional cardiologist and a cardiac surgeon really do the procedure together.

**G. MICHAEL DEEB:** And here at the University of Michigan, we've done that to the highest level. I think this helps a patient who's getting a transcatheter valve, because the cardiologists have superiority in wire skills. And the surgeons have a long history and superiority of anatomy and the angles, and how to lay a valve in there to the best benefit. And so when you have the surgeons and the cardiologists working side by side at the table the whole time, both with a vested interest in that patient, I think you get the highest level of care.

**STAN CHETCUTI:** I would say 90% of the work is not the procedure itself, it's preparation for the procedure. We have people who schedule cases, people who talk to the patients and act as their patient navigators. We have nurse practitioners who become true partners with our patients and act as their advocate throughout the whole process. Most of our patients will build a very strong emotional bond with their caregivers, even before the procedure is done, because we are completely embraced and enmeshed, and we want them to be partners in the whole procedure.

**HIMANSHU J. PATEL:** They're seen at least by one, perhaps two surgeons, and by one of our cardiologists as well. And then they are presented at our multidisciplinary conference, where members from cardiac surgery, from interventional cardiology, from our imaging cardiology group, from our nurse practitioners and anesthesiologists who would be helping care for these patients are all present. And collectively, what we do is we present the patient and come up with the best options for them before we make a final recommendation to the patient.

**STAN CHETCUTI:** One very important element of our program is the long-term follow-up. We are very proud of partnerships we have built with our referring doctors, who we consider partners in the care of our patients, and also with the patient's long-term care in general. There's one of us always on call to be able to address concerns, issues, and specifically, anything that may come up, no matter how out of the ordinary it is. It is very important that we do not consider patients to be a number. We are just really and truly privileged to have them be part of our process, and have us be part of their process.

**P. MICHAEL GROSSMAN:** One of the wonderful things about being involved in this program is that I get the opportunity to work with patients and their families, and see a patient going from being incredibly limited, short of breath, can barely get out a sentence, to coming to see us in clinic at their follow-up visit just a few weeks later, after their transcatheter aortic valve replacement, and now they're walking. They come into clinic with a big smile on their face. They're talking about what they've

done over the last few weeks with their family, and things that they haven't been able to do in months or even years, and about their plans for what they want to do in the future.

**HIMANSHU J.**

TAVR, which is now a commonplace phenomenon, really wasn't that way about 10 years ago.

**PATEL:**

The patients who we treated first were those patients that were not candidates for open-heart surgery. And what has happened over time is that as the success of this technology has been demonstrated in those patients, we have then started treating patients with lower and lower risk.

And our hope is in five or 10 years, that the majority of patients with degenerative aortic stenosis will be candidates for a catheter-based therapy to improve quality of life, to improve recovery times, and to get patients back up on their feet and feeling like normal people much quicker.

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