

Melanie Cole: Welcome to the podcast series from the specialists at Penn Medicine. I'm Melanie Cole and I invite you to listen as we discuss mitral valve disease, when it's appropriate to refer, indications and treatment options.

Joining me is Dr. Gene Chang. He's an Assistant Professor of Clinical Medicine and the Director of the Cath Lab at Penn Presbyterian Medical Center of Penn Medicine.

Dr. Chang, it's a pleasure to have you with us today. To start, would you tell us a little bit about the types of valves being used to treat valvular disease today and the issues we've had with these devices?

Dr. Chang: I would say for tissue valves, for surgical valves, they honestly continue to get better, but unfortunately the durability of these valves is a limiting factor. So you'll see a few number of valves fail within the first couple of years, but the durability is not much longer than 10, 15 years and so forth. So that's a major limitation for these patients that undergo surgery and have bioprosthetic valves placed.

Melanie Cole: Well, in the last few years, the treatment of aortic valve disease has evolved rapidly and much of the progress is linked to Penn Heart and Vascular. Briefly sum up for us the transcatheter aortic valve replacement or TAVR program at Penn Medicine and MitraClip therapy, both of which were investigated at Penn Medicine.

Dr. Chang: Sure. It's an interesting parallel. The whole TAVR or transcatheter aortic valve replacement program was really sort of brought in as a clinical trial, looking at patients that were high risk to survive aortic valve replacement in the traditional surgical operation.

And, as you know, there was benefit for those patients that were particularly inoperable and in those patients undergoing surgery that were high risk by certain criteria for complications and mortality from surgery.

It's interesting to take a look at the volume of surgery for aortic valve replacement versus transcatheter-based. And there's almost about 80% of the isolated, maybe even 90%, of the isolated valve procedures are transcatheter-based now as opposed to surgically-based. But that is a course evolution has taken about 15 years in the making.

And it's sort of almost the same investigators taking a look at the mitral valve space here within the Penn Health System taking a look at those that are inoperable or at high risk of complications and comparing a transcatheter-based implant of a device specifically the MitraClip here versus surgery. And now, it is FDA approved for such patients if they meet appropriate criteria. And there are trials now beginning and ongoing for moderate risk. So time will tell to see if we follow the same timeline and pathway with mitral valve and mitral regurgitation.

Melanie Cole: Dr. Chang. So MitraClip is used in edge to edge repair of the mitral valve for mitral regurgitation. Developing treatments for these repairs have been more challenging than that for other mitral conditions. Tell us why that is.

Dr. Chang: Well, as I was mentioning, it's been a little bit easier in terms of aortic valve, because the pathology is relatively uniform in terms of the problems that causes stenosis. Mitral regurgitation, it has a less sort of a uniform anatomy. It's not sort of circular, it's much more oval-shaped and there are different mechanisms in terms of why an individual would have significant mitral regurgitation.

And the two broadest categories have been broken down into primary or degenerative versus functional and secondary. And in the former, it's really a problem of the mitral valve leaflets or the

mitral valve apparatus, whether they have torn, they have some flails or they prolapse or so forth, but it's a primary problem of the leaflets.

Whereas in the latter, secondary mitral regurgitation, it could be a problem associated with the ventricle itself or something that happened to the ventricle in terms of causing inadequate movement or inadequate coaptation, if you will, where the leaflets are supposed to come together and not allow a leak, kind of like having a door shut without any air getting through it.

And I think that the differences of how the pathophysiology of, or the origination of, this mitral regurgitation has certainly made it challenging. But there is a lot of interest as you know in a lot of companies and a lot of individuals looking at ways to tackle this challenging problem.

Melanie Cole: Well, along those lines, MitraClip was originally approved for Medicare reimbursement for patients with degenerative or primary, but was recently approved for secondary. So what does that mean for referring physicians?

Dr. Chang: It's exciting. MitraClip for degenerative MR was originally FDA approved back in 2013 and has gained sort of CMS reimbursement in 2015. But FDA approval for this secondary or functional MR Indication and was just approved with respect to CMS reimbursement in this year in January. And I think that makes a huge difference in terms of hospitals, health systems, and so forth, being able to viably provide this service to a great majority of patients.

The degenerative mitral regurgitation really should be treated surgically, unless there are sort of contraindications or limitations or so forth from a surgical standpoint in terms of the patient.

That leaves a broad category of patients that were never really getting treated that adequately with this device, this functional MR, because there was really not great data for surgical options. And when the data came out from the COAPT trial, that was absolutely amazing and stunning. Now, we can offer this therapy to a lot of patients that we didn't necessarily have before.

Melanie Cole: Speak about the multidisciplinary approach as a team approach is becoming increasingly important for mitral valve surgery as a heart surgeon at Penn Heart and Vascular. Can you touch on why it's important to have this collaborative partnership between interventional cardiologists, heart failure cardiologists, surgeons, imaging specialists?

Dr. Chang: This multidisciplinary approach has been absolutely exciting and has been highly educational for me, in terms of looking at and gaining a better understanding of my echocardiography colleagues, my surgical colleagues, and so forth and my heart failure colleagues. And it's absolutely critical, I think, in this disease to have a very collaborative and a very strong interactive multidisciplinary program.

So for instance, I think as I was mentioning the degenerative patient that has mitral valve prolapse or flail can get repairs of these valves with excellent outcomes, and that is really the best and it's potentially curative for the patients.

So they should have an evaluation and that evaluation should look at is it repairable or does it need to be replaced? How high of an operative risk is this individual? And then if they're deemed to be extremely high risk for whatever particular reason, you might want to step back and say, "Well, yeah, I could do the surgery, but I may not do the patient a lot of service if they have a lot of complications."

And then if you take a look at the other arm, if you will, or the other category, this functional or secondary MR, data really comes and we're highly dependent upon these patients getting optimized for their congestive heart failure or other symptoms, because remember this is not necessarily a

primary problem of the valve, but it may be a secondary result based on heart function of the individual patient and so forth.

And like any operation, any surgery, the better you are before the procedure, the better you're going to do after the procedure. And we have our patients see our heart failure colleagues. We talk together. We decide when the appropriate time for the procedure is going to happen, if they're candidates. And again, it's highly dependent upon a review of the anatomy with our echo colleagues, we do get all four groups involved in almost all the discussions of these patients.

And then we also are dependent upon our administrators and our nurse practitioners who really keep us in line and in check and organized about where the patients are, what studies they need and so forth. So it's a big endeavor to do this in as efficient and as productive a manner as possible. It's exciting. I think it's a whole new realm.

Melanie Cole: Well, it certainly is. And doctor finally, what has you most excited about the future of catheter-based intervention for mitral valve repair and replacement? And when do you feel that it's important and appropriate to refer to the specialists at Penn Medicine?

Dr. Chang: It's never too early, I think, to have the patients referred, if there's any concern about the severity of the mitral regurgitation or the clinical scenario that the mitral regurgitation is the primary driver of whatever symptoms and co-morbidities their patients are having.

Melanie Cole: Thank you so much, Dr. Chang, for joining us today and sharing your incredible expertise. That concludes this episode from the specialists at Penn Medicine. To refer your patient to a specialist at Penn Medicine, please visit our website at pennmedicine.org/refer or you can call (877) 937-PENN. Please remember to subscribe, rate and review this podcast and all the other Penn Medicine podcasts. I'm Melanie Cole.