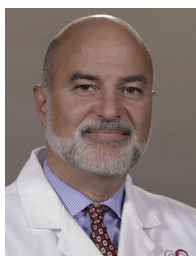


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**Key Words:** mitral valve replacement, prosthetic durability, mechanical, bioprosthetic, Melody valve, congenital heart surgery

## Discussion

**Presenter: Dr Sitaram M. Emani**



**Dr Emile A. Bacha** (*New York, NY*).

Ram, excellent presentation and excellent study. This is a great paper that can potentially change the way we practice pediatric cardiac surgery in that particular field. You've shown that it matters what kind of mitral prosthesis is used in kids, and that, at 10 years, only three

quarters of the patients are alive, which is a sobering reality in itself if you think about it. Fixed-diameter tissue valves have worse outcomes in that patient cohort compared with mechanical and Melody valves. You've shown that contrary to what is commonly stated and believed, mechanical mitral valves have a median time to reoperation of 11 years, which means they are not a lifelong solution, as a lot of our colleagues like to think. You also have a commendable median follow-up, so the data I think are valid and quite good. I have several questions. The first one is: why do you think that mechanical valves did not have a greater incidence of bleeding and thrombosis compared with the other valves? That is really a counterintuitive finding.



**Dr Sitaram M. Emani** (*Boston, Mass*).

I agree; I was certainly surprised by the lack of difference in bleeding and thrombosis between mechanical and bioprosthetic valves, although I expected to find superior durability of mechanical valves. One weakness of this study is that it is a retrospective review of medical records and we obtained

as recent follow-up as possible, so we may have missed a few events. Since we have an anticoagulation service that follows all patients on warfarin therapy, the patients who received warfarin are followed very carefully and managed very carefully, particularly at our institution. Many families are initially reticent to have chronic anticoagulation therapy, but at follow-up, they report that warfarin not as bad as they thought it was going to be. We did not assess quality of life, however. I think we would need to prospectively assess the burden of warfarin in this population to allay misconceptions surrounding anticoagulation.

**Dr Bacha.** The second question, and maybe the most important question is: are you ready to completely discard fixed-diameter in the mitral position in the pediatric population to go with either a mechanical valve or a Melody valve? That is what your presentation seems to imply.

**Dr Emani.** I think that my practice has certainly shifted in that direction. I'm still somewhat biased by families who request a non-mechanical option. If diameter is less than 19 mm, I would use Melody. If the annulus is 19 mm or greater in diameter, and there are no contraindications to anticoagulation, I would recommend a mechanical valve. If the annulus is 19 mm or greater, and anticoagulation is not recommended, then we would use bioprosthetic valve, most likely porcine prosthesis.

**Dr Bacha.** The fact is that you can use a Melody valve in most patients. If you are going with a non-mechanical valve option, the Melody valve is an option, even at larger sizes.

**Dr Emani.** I agree. The contraindications for the Melody valve with the current design really have to do with the dynamics of ventricular size and the risk of left-ventricular outflow tract obstruction. There is room to improve the design of these expandable valves for pediatric applications, which I think could play a very important role in the future. I don't think the Melody valve has much advantage for sizes greater than 19 mm, since it really cannot be dilated much beyond 22 mm.

**Dr Bacha.** The final question is that you had a 12% incidence of paravalvular leaks with the Melody valve, which we both know is a common and difficult problem to manage. What is your current technique for implantation of the Melody valve in a few brief words?

**Dr Emani.** I usually use a 2-layer purse-string suture, followed by a couple of anchoring sutures to implant it. Most of the paravalvular leaks occurred I believe because the valve skirt, which is sutured onto the stent, can separate from the stent. Similarly, the wall of the jugular vein which is sutured to the stent, can actually separate from the stent itself. If this type of perivalvular leak develops, it becomes hard to fix. Again, I feel these issues can be rectified by altering the design of the valve to avoid surgical modifications on the back table prior to implantation.



**Dr Richard Shemin** (*Los Angeles, Calif*). Very interesting study, I have 2 questions. One is about the impressive results with anticoagulation in this cohort. I was wondering if you use home international normalized ratio (INR) testing to help improve the outcomes or not?

**Dr Emani.** Yes. We have a dedicated anticoagulation team that follows all of our patients on warfarin after discharge. We do use home INR monitoring, and the system is validated in the hospital before discharge. During follow-up a combination of the home INR monitoring and in-lab monitoring is used.

**Dr Shemin.** At the time of reoperation, what are the valve strategies and choices that you've made? Is there a percutaneous valve-in-valve option for the people who get biological valves?

**Dr Emani.** In the patients receiving a 19-millimeter or greater sized valve, I think there is an option for percutaneous valve. Our interventional cardiologists typically prefer a child to be 35 kilograms to perform it. With regards to valve upsizing of fixed-diameter valves, we can typically upsize by 2 millimeters in diameter. With the Melody valve, we have the ability to expand the valve by sequential balloon expansion; we can typically expand a valve that is less than 15 millimeters at implantation to a maximum diameter of 21 millimeters. This means that at the next replacement, we can put in a valve that is at

least 21 millimeters in diameter. The ability to grow the annulus is one of the advantages of expandable valve technologies.



**Dr Hani Najm** (*Cleveland, Ohio*). Since the Melody valve sits in the left atrium, any comments about clot formation around that Melody valve on explantation? Have any of the come close to the pulmonary veins and disturbed the flow in smaller atriums?

**Dr Emani.** We haven't seen issues with pulmonary vein compression stenosis or obstruction. Pannus formation on the outside housing of the valve can be seen on reoperation, but we have not seen thrombosis or thrombosis-related complications. Most of these patients are treated with aspirin with platelet tested before discharge.

**Dr Najm.** Any explanation as to why transplants are worse in the bioprosthetic?

**Dr Emani.** The transplant-free survival data deserve very close attention. In adult patient populations, we are starting to see differences in survival based upon valve type, with bioprosthetic valves associated with greater risk compared with mechanical. Certainly, selection bias could be at play, with greater-complexity patients undergoing bioprosthetic valve implantation. However, the difference cannot be ignored. It was difficult to tease this out in our small data set, so we need a randomized trial to address this concern.