**Title: TCT 24: CLASP IID: Two-Year Outcomes of Transcatheter Edge-to-Edge Repair for Degenerative Mitral Regurgitation**

**Participants: Dr Firas Zahr**

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**Dr Firas Zahr**

**What is the reasoning behind this study?**

You know, the CLASP IID study is designed to look at patients who are prohibitive surgical risk for symptomatic severe mitral regurgitation from degenerative mitral valve disease. And the study has two arms: those who would qualify for MitraClip based on the IFU of the MitraClip were randomized to either the PASCAL device or the MitraClip in 2:1 fashion, and those who are not deemed suitable for randomization were followed prospectively in the registry arm of the study.

**What was the study design and patient population?**

So, the patient population is, you know, prohibitive surgical risk, so older patients, you know, a lot of them were frail, multiple comorbidities, but they were all symptomatic with three plus or greater mitral regurgitation. They have to have degenerative mitral valve disease. And again, the study has 2:1 randomized arm and a registry arm.

**What were the key findings?**

Yeah, so we followed both arms of the study, and we presented, last year, we presented the one year data, and this year we're presenting the two year data, you know, for those patients. And we looked at reduction of mitral regurgitation, rehospitalization, cardiovascular and non-cardiovascular mortality as well as if there was any mitral valve reinterventions.

And what we have found is the reduction in mitral regurgitation that happened after the procedure was sustained to up to one year, which was presented last year, and now up to two years, which is the results we are presenting today. And I think what we've also noticed that those patients who have MR reduction to one plus or less, which is what we thrive for, made a majority of the MR that was reduced, and those results were sustained up to two years as well.

**Were there any surprising or unexpected results?**

I mean, I wouldn't call it, I wouldn't call it surprising, but I would say we were all a little nervous about those patients in the registry because they're not straightforward anatomy, they're sicker patients, they have complicated anatomy. And we always were nervous and they were never followed prospectively. So we were nervous about what the results of those patients going to look like and whether or not the acute reduction of mitral regurgitation is going to be sustainable.

And the two year data has re-emphasized that the reduction in MR is sustainable. It did not come at a cost of increased gradient, despite the fact that those patients have complicated anatomy. And it was associated with positive remodeling of the ventricle as well as improvement in New York Heart Class Association and quality of life for the patients.

So in that way, we were nervous about those groups as the first trial that followed them prospectively with a core lab as well as adjudication committee, and we found that the results were sustainable.

**What further research is needed, and what are the next steps?**

Yeah, so we're very excited about all of the data that is coming out, including the long term fallout for the CLASP IID, increasing our confidence in treating the complex anatomy, the broader patient population with severe mitral regurgitation with TEER. I think this is very good signal that TEER continue to have good outcome that are long-term sustainable. You know, obviously we are continuing to follow those patients, and we're following those patients up to five years. So the long term follow up data will continue to be available for us as well.