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Key Words: mitral regurgitation, mitral repair, mitral valve, beating heart mitral repair, epicardial repair, minimally invasive mitral surgery

Discussion

Presenter: Dr Isaac George

Dr Andrea Colli *(Pisa, Italy)*. Good evening everybody. I would like to thank the American Association for Thoracic Surgery for the privilege of discussing this very interesting manuscript and presentation. First of all, I would like to congratulate Dr Isaac George and the coauthors of the study from Vilniaus; they are always on the first line of innovation. This new device is substantial in that it highlights an epicardial mitral annuloplasty and shows very nice and interesting preliminary results. The feasibility of the procedure is being demonstrated. During your presentation there was a nice demonstration of your new device that allows mitral valve coaptation and creating septal-lateral reduction.

I would like to ask you a few questions. Based on the fact that I've seen that the septal-lateral dimension is significantly reduced, there is a proportionate increase of co-optation length based on the reduction of the septal lateral dimension. But the reduction, in terms of regurgitation, even if it is statistically significant, doesn't seem to be extremely big in terms of volume.

The second question is about the sizing of the device. You stated that the sizing was performed off-pump, but there was a preoperative planning applied for the sizing and if yes, there was the 2 sizing—the real 1 and the preplanning. Were they similar or not?

Third question: You said that it is an off-pump procedure basically. Was it difficult to place the device and also to fix the device to the ventricle because of the off-pump procedure combination? And finally, based on the are very nice result that you presented, we can consider it as a ventricular remodeling device more than an annuloplasty because of the volume's reduction of the ventricle and a little bit less probably on the septal-lateral reduction. Thank you very much.

Dr Isaac George *(New York, NY)*. Thank you for your great questions. Those are excellent observations. I'm going to start with the first question about mitral regurgitation (MR) reduction. I believe the question was why MR reduction didn't track quite as well with the volume reduction. Is that correct?

Dr Colli. Yes.

Dr George. That's a good question and a good point. At the end of the day, there are 2 components to these ischemic mitrals, and I think the ability to maintain that posterior portion of the left ventricle, which is a very vulnerable area in ischemic MR and really is the tethering portion for the posterior papillary muscle, is among the keys for this. These patients started with potentially effective regurgitant orifice areas or volumes that weren't necessarily always huge; some of them were smaller. And MR is potentially very dependent on many different things.

I think the structural results were very consistent. The MR reduction can be based on a lot of different things, including pharmacology, medical therapy, and heart failure management. I think we'll have to see where these patients really end up. And I think understanding this in the framework of where they're starting out with proportionate or disproportionate; however much we believe in the framework or concept it may help us understand: is their MR significant, and is it because of the left ventricle, or is it a primary problem of the valve itself?

So I'm happy that both functional components were improved. I'm even happier, you know, impressed that the volumes were improved and the structural geometric components were improved rather than focusing just on a quantitative component of MR.

I do think that looking forward, I will look less at effective regurgitant orifice potentially and even regurgitant volume but look at regurgitant fraction, which is I think a more physiologic parameter for an individual patient, which may be a better surrogate than some of these other things that we're looking at. So I think that's

something that we should we should look at moving forward.

The question of preplanning is something that with such small numbers, it's been very difficult to quantify and understand. Not all of the patients had computed tomography scans; some of them did, but going back and trying to figure out how to correlate what their preplanning size was and what we modeled beforehand and in the operating room as well as figuring out an algorithm or a rubric to do that is the next step. We haven't been able to do that entirely right now.

I think there's a dynamism in the operating room that we have to appreciate and I think being off-pump is great for patients, but it also becomes a little more challenging, especially when you're lifting the heart. You may have temporary ischemia, you may have temporary changes to the heart where the heart dilates. And so the sizing is very dynamic and I think we have to understand the sizing from a preoperative standpoint to an intraoperative standpoint and then see how that correlates to the immediate and then late-postoperative time periods. That's a key point for us to do this—have it validated and have it reproducible. If we're not able to do that, if we're not going to be able to do this well, and I think that's something that we can learn from our structural field that we can use these tools to do that. So I think that will come with time and in the next set of studies doing very detailed measurements and correlating that intraoperatively.

The difficulty of on-pump versus off-pump is a great question, and I think we'll open it up for discussion at some point. My internal sense in my own head and in my own practice would be that I would do this right before I go on pump or right after I go off pump. Size initially, but keep volume in the heart and then actually place the device just as I'm finishing my distals and before the proximals. And then come off and make sure I'm happy with that result. It doesn't necessarily allow you to always do the real-time adjustment that they did in the off-pump procedures in Lithuania, but I think that's another question—whether it's going to be easier to do this off-pump after you finished all your grafts or if you're going to be sacrificing lifting the heart up and placing this, and the time it takes to do that and secure it would be disadvantageous to a procedure or to a patient. So I think getting an efficiency for that will be important as well.

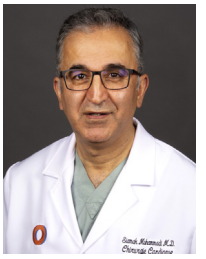
But my sense is doing a preplanning sizing right before you go on-pump and then placing this with the heart filled and then securing it after you do your distals is what I would imagine we do. And then the question about left ventricle remodeling (why does it remodel)—I think that the posterior flap really has to be able to support the portion of the posterior basal annulus as well as the area near the papillary muscle. We can always make that longer, we can make it shorter, but that's a really key component to supporting the left ventricle. Hopefully the remodeling aspect retains those features long-term.

Dr Vinod H. Thourani *(Atlanta, Ga)*. That's great. Thanks so much to both of you. We have a minute or 2 for any comments.

Dr Tsuyoshi Kaneko *(Boston, Mass)*. Great presentation. A quick question about the device: Does this clip compromise the flow to the coronary arteries? Do you have to watch out for the arteries? Do you confirm with an angiogram pre and post? How do you confirm that the coronary artery, especially in that circumflex, is not compromised?

Dr George. There's no way 100% other than clinical measures and indicators such as ischemia, grossly looking at coronaries, but the amount of force that's on there is actually not significant enough to do that. It's going to have to be confirmed with an angiogram and the next set of protocols as mandated by the Food and Drug Administration with either an intraoperative or postoperative angiogram or a coronary computed tomography angiography while in hospital or 30 days. But that's a good question.

Dr Thourani. For the US early feasibility trial, there will be a preoperative gated computed tomography angiography that will give us good anatomy of the region for the circumflex coronary artery.



Dr Siamak Mohammadi *(Québec City, Québec, Canada)*. Great talk, Dr George. Do you have any data on myocardial viability in these patients; do all the patients have concomitant coronary artery bypass grafting?

Dr George. That's a good question. We don't. I can look back and see what the angiograms look like and maybe get a sense of that.

Dr Thourani. That is a good question because obviously you can get improvement in a lot of the ventricular dynamics just based on revascularization. Great job. Thank you, Dr Colli and Dr George.