VUYISILE T. NKOMO: Greetings. I'm Dr. Vuyisile Nkomo, Cardiologist and Co-Director of the Valve Clinic at Mayo Clinic. Today on the heart.org we'll be discussing recent updates presented at the ACC on the TAVR trials, along with the TVT Registry and CHOICE trials, with my colleague, Dr. David Holmes, who specializes in interventional cardiology and is co-author of the TAVR trials. Welcome, David.

DAVID HOLMES: Well, it's great to be here with you. Indeed, ACC meeting was rich with data on TAVR It was a terribly exciting time.

VUYISILE T. NKOMO: Excellent. Now, recently at the American College of Cardiology, 2012 Scientific Sessions, you presented one-year outcome's data from STS/ACC TVT registry. Could you summarize for us what the TVT Registry is, and the main lessons learned from it so far?

DAVID HOLMES: Sure. The TVT registry was set up by the professional societies as a result of the national coverage determination issued by CMS. The intent was to capture all patients in the United States undergoing TAVR, so that you had the full denominator of patients. So we could then look at post-market surveillance issues, post-market approval issues in the entire group of patients.

And so that goal has really been achieved. The focus of this specific paper was to combine the initial in-hospital data from the TVT registry with CMS administrator claims data at one year. We hadn't done that in the TVT Registry before. So we then identified almost 6,000 patients who had linkage of CMS administrative claims data with the TVT data, to look at then, those variables that are not cause and effect, but associated with one-year mortality.

VUYISILE T. NKOMO: OK So what did you find that was newsworthy?

DAVID HOLMES: So we looked at the associations. And number one, we then looked at some risk factors. And those risk factors associated with one-year mortality were different than the risk factors associated with one-year stroke. It was an interesting group of differences in variables.

So when you look at the mortality, which at one year was 26%, the specific variables associated with mortality were number one, age, which you could imagine-- advancing age had more mortality-- male gender, severity of Chronic Obstructed Airways Disease, more abnormal left ventricular dysfunction. A striking component of that was that small group of patients that were on dialysis had a one-year mortality of about 45% to 50%.

And so that was staggering, in terms of the importance of that. And the final piece of information related to a one-year mortality was that those patients that had higher STS-predicted risk of mortality had higher mortality, indeed. When you went to the flip side of that, when we looked at those same risk factors, and association with stroke at one year, the only thing that was identified as being significantly associated was female gender. Everything else sort of washed away.

VUYISILE T. NKOMO: What do you think explains that?

DAVID HOLMES: I think there are several different things. Number one, they may have more left ventricular hypertrophy and subendocardial ischemia. And That's been seen, that their patterns of hypertrophy to structural overload may be different than men.

Number two, they have a smaller vascular tree. And so they have the potential for more complications. Number three, it might relate to the fact that even though STS-measured score wasn't different by virtue of the downside of STS score and all those scoring systems, maybe they were sicker. And the final piece of information is that finding with more strokes in women has been seen in other fields in cardiovascular disease, such as atrial fibrillation and stroke risk.

VUYISILE T. NKOMO: But at one year, they seem to do better than men, in terms of outcomes?

DAVID HOLMES: Yes, correct. So men had more mortality. Women s more stroke.

VUYISILE T. NKOMO: Interesting.

DAVID HOLMES: Those factors, then, will be able to be studied in the development of risk-specific models for TAVR, which we don't have at the present time.

VUYISILE T. NKOMO: OK, great. Now, one of the other issues that comes up when talking about TAVR is this issue of futility, that some patients don't benefit from TAVR at all. Can we glean anything from the TVT Registry and all the data accumulated so far, about this issue of some of the patients not benefiting at all from TAVR?

DAVID HOLMES: Sure. Those are, as you know, cohort C patients, who die with aortic stenosis rather than die from aortic stenosis. We are working on that because it is such of fundamental importance. The surgeons have done studies like that in the past, looking at five or six-minute walk tests and other indices of frailty.

I think that we will identify good indices of frailty, which will identify those patients that are probably not going to be very well off at one year. It was of interest in the TVT Registry of those patients that were followed for six months, about almost 60% were alive and had not needed repeat hospitalizations. So in terms of quality of life, that's a huge deal, to be able to keep them out of the hospital.

VUYISILE T. NKOMO: That's great. Excellent. So let's shift focus a little on some of the other news from the ACC, related to the CoreValve. The period trial, which was performed across 45 centers in the United States, comparing TAVR with the CoreValve, versus open heart surgery for patients with symptomatic severe area of stenosis at high surgical risk. This was also presented at the ACC.

Now the procedural success with TAVR with the CoreValve was about 99%, which is pretty interesting, and good. Their surprising finding, at least to me, was that TAVR was superior to surgery at one year. Already this is being perceived as a paradigm shift, favoring the use of TAVR in high-risk patients with severe aortic valve stenosis. Could you give us some insights regarding that design of the trial, the patient population studied, and whether we can believe that TAVR is superior to surgery in high-risk patients with severe aortic valve stenosis.

DAVID HOLMES: Sure, those are great questions of fundamental importance for the field. That trial is particularly seen as something that may change how we're going to treat patients. There are some specific things about it.

Number one, the STS predicted risk level of mortality was lower than was seen in the PARTNERS trial. Now, that is either a good thing or a bad thing. What has happened is, as we become more familiar with the technique and the technology, we're going to probably see some risk creep.

And we will then do this in lower-risk patients. So their predicted risk using the STS score was about 7.5. And indeed, some of the patients were less than 4. So that would be lower-risk patients.

So the striking thing about this is to say that number one, both surgery and TAVR outperformed what had been predicted. That's the first piece of information. But the second piece of information is that there was a survival benefit that really hasn't been seen before. We've seen a lot of non-inferiority.

But we haven't seen superiority like this. There were some differences in the patient population. So for example, the patients who underwent surgically-ordered valve replacement, there were more diabetics. Whether that could have impacted on this degree of mortality reduction with TAVR is not at all clear.

The device is smaller, and that is true. The other things that were important is that there was a very high incidence of acute kidney injury in the surgical group. Much higher than I would have thought before.

So I think there were some differences. Is this intriguing? It clearly is. Is it going to increase interest in the whole TAVR space? It clearly is. And I think that it will be part of the migration as we move more towards lower and lower-risk patients, in addition to the very, very high-risk patients.

VUYISILE T. NKOMO: That's interesting. Now, the CHOICE trial, also presented at the ACC, also has some information about CoreValve. So This is a study comparing a head-to-head comparison of the CoreValve with the Edwards XT Valve.

And they found, in that trial across about five centers across Germany, that the Edwards XT valve performed better than the CoreValve. And could you comment on the differences between the two valves, as the Edwards XT valve and the CoreValve? And if the design and results of the CHOICE trial prove that the Edwards Sapien XT Valve is better than the CoreValve?

DAVID HOLMES: Sure, and those are great questions. I think it is of fundamental importance that it is rare that one specific trial completely changes everything. And I think that's probably the case, particularly a comparative trial.

This was a relatively small trial, about 240 cases. Done in those Experience Centers, as you talked about. And the results were surprising.

So you then have to balance the CoreValve one year versus this trial, which is smaller, which shows very different things. It shows that number one, the first one showed that it was superior to surgery. Other results in the field, however, have said that the balloon-expandable valve was non-inferior to surgery.

And then you have CHOICE, where you then say, well, when you compare balloon-expandable versus self-expanding, that balloon-expandable wins. So there's something that doesn't fit between those. Is it an intriguing piece of information? It clearly is.

The majority of the difference was seen in the degree of paravalvular leak. And there have been some concerns that indeed, paravalvular leak might be increased with the use of the self-expanding stents. There were other things that were different, in terms of post dilatation after you deployed it. Well, that's part of the need of that procedure to be done.

So I think that it is interesting data. I don't think it solves everything, by any means. I think that these will settle out, in terms of different patients being treated with different devices, depending upon what the size of the vascular access is, number one. Depending upon the specific anatomy of the annulus and the distance between the annulus and the coronary ostium. Which, as you know, can be a problem, because you could occlude a coronary ostium.

So I think it's intriguing data. I don't think it's going to settle the issue. I don't think we're going to immediately say gosh, we should not do any self-expanding stents, because self-expanding stents are now superior to surgery.

VUYISILE T. NKOMO: Great That's great. Thanks, David, for those great insights.

DAVID HOLMES: Well, it was a great meeting for TAVR.

VUYISILE T. NKOMO: Excellent.

DAVID HOLMES: Good.

VUYISILE T. NKOMO: And thanks to our viewers. I hope you will continue to check out future content on Mayo Clinic's page at the heart.org, on Medscape.