I am Dr. Raj Makkar from Cedars-Sinai medical centre in Los Angeles.

What is the rationale for this study?

Well, transcatheter aortic valve replacement has become a very acceptable treatment for patients with aortic stenosis based on pivotal randomised clinical trials that have been done in the last decade. But, however, these trials excluded bicuspid aortic stenosis anatomy. So in young patients, as we, you know are treating more and more younger patients, almost 50% of these patients have bicuspid anatomy. It is therefore imperative that we have more data on the use of TAVR in patients with bicuspid aortic stenosis.

Describe the design, patient population and endpoints?

In the United States, all transcatheter aortic valve replacement procedures are registered in a registry, it's called the SDS ACC TVT registry. So, this data set essentially provides us an opportunity to look at all patients with TAVR, including patients who had bicuspid aortic stenosis and an event transcatheter aortic valve replacement. So, between 2015 and 2020, there were almost 150,000 patients that underwent transcatheter aortic valve replacement with the balloon expandable SAPIEN 3 or SAPIEN 3 ultra valve. And of these, more than 30,000 patients actually were low risk for surgery. Our primary goal here was to see what are the outcomes of transcatheter aortic valve replacement in patients who have bicuspid aortic stenosis and who are low risk for surgery. So, essentially in the entire dataset, there were more than 7,000 patients with bicuspid aortic stenosis, and more than 3,200 patients actually were bicuspid aortic stenosis and were low risk for surgery. We looked at the outcomes of TAVR in these patients and we compared them to the outcomes of patients with tricuspid aortic stenosis by performing what is called a propensity one-to-one matching.

What are the key findings and what conclusions can be made?

What we found was that in these low-risk patients where the average age was less than 69 years, both for bicuspid and tricuspid aortic stenosis, the STS was 1.7, which means that the expected mortality was 1.7% at 30 days. When TAVR was performed, the outcomes were actually quite good. The intra-procedural outcomes were good in hospital mortality in patients with tricuspid aortic stenosis was 0.6% compared to 0.4%. You know, in patients who had tricuspid aortic stenosis, similarly the stroke rates were around one or 1.2% in both bicuspid and tricuspid aortic stenosis. So, similar outcomes, in terms of death and stroke, were also seen at 30 days and one year. So at 30 days, the mortality from TAVR or mortality in patients who had undergone TAVR with bicuspid aortic stenosis was 0.9%. So this is pretty good. This is, you know, comparing it to patients with tricuspid aortic stenosis and comparing it to the published literature with surgery, with bicuspid aortic stenosis, our conclusion was that at 30 days, these outcomes are quite competitive. In addition, they're looking at the mortality and stroke rates at one year. Once again, what we found was that the mortality with bicuspid aortic stenosis at one year was about 4%. And similarly with tricuspid aortic stenosis it was about 6%. So, our conclusion is that these end points of death and stroke are similar between bicuspid and tricuspid aortic stenosis in patients who are at low-risk for surgery. The intra-procedural outcomes, including conversion to open heart surgery were very low in these patients. Similarly, the rates of re-intervention after bicuspid aortic stenosis were also quite low, you know, after TAVR. We also looked at the echocardiographic outcomes, which is the gradients and the valve areas and there were similar. We also looked at the functional measures which is quality of life, you know, in terms of the improvement in KCCQ scores and the improvement in NYHA class. And they were quite impressive and similar between bicuspid and tricuspid aortic stenosis, indeed, at one year almost 95% of the patients that had undergone TAVR for bicuspid aortic stenosis were in NYHA class one or class two. So, I would deduce that, based on these results, we feel that, you know, in selected patients, the TAVR is actually a very reasonable alternative to surgery in patients with bicuspid anatomy.

Which patients would benefit from TAVR based on these findings?

So, the way TAVR is performed in the United States is with a heart team approach. Specific anatomical characteristics were not collected in the TVT registry, and we do know that morphology can play an important role in the outcomes of TAVR after bicuspid aortic stenosis. So that, in a way, is somewhat of a limitation of the study. But nonetheless, what can be said is that if the heart team decides, after evaluating clinical aspects of the patient and the imaging characteristics of a patient, at least in the United States, in this consecutive series of patients, when TAVR was performed the outcomes were actually quite good.

What are the next steps?

I think we need to gather more data, precisely to guide what anatomical characteristics should dictate the patient undergo TAVR versus surgery. We have performed one such study, but I think we need to do further work in that area. And finally, I do believe that it would be ideal to do a randomised clinical trial between surgery and transcatheter aortic valve in patients who have bicuspid aortic stenosis and who are at low risk for surgery.