Title: **Repeat TAVR Outcomes: Promising Results for Selected Patients with Failed TAVR**

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Dr Raj Makkar:
I'm Raj Makkar, I'm an interventional cardiologist at Cedar Sinai Medical Centre in Los Angeles.

What is the importance of this study?

So, as transcatheter aortic valve replacement is being now used in younger patients who are likely to outlive the durability of the bioprosthetic valve, it is important for us to gather data on the safety of a repeat transcatheter aortic valve replacement.
The reason why this data is important is because it also will help us decide if repeat TAVR procedure is a viable option, then when we are making a decision whether it is surgery or transcatheter aortic valve replacement the first time around, that information can be used and integrated in making that decision.

What was the study design and patient cohort?

Essentially, it's an observational registry and in America every single patient who undergoes transcatheter aortic valve replacement is enrolled in what is called the Transcatheter Valve Therapy Registry. It's a registry that is supported by the American College of Cardiology and Society of Thoracic Surgeons. And there is ability for us to do multiple analyses from this registry because there is systematic follow up.
There is also echocardiographic information that is gathered and quality of life parameters that are gathered as a part of this registry all the way up to one year.
In addition, there's also ability to cross link the patients that are in this registry with the Medicare claims database beyond one year, which also allows us to look at the follow up beyond one year.
So, our goal was to see how many patients have undergone redo TAVR in this registry and what their outcomes are and how do these outcomes compare with the outcomes of patients who were undergoing TAVR for the first time. There were 1320 patients who over a period of ten years almost had undergone repeat TAVR procedure.
And what we did was we took this 1320 patients and we matched them with patients who had undergone TAVR for the first time, because there are many more patients, there are almost 300,000 patients that have undergone TAVR with balloon expandable valves and we wanted to compare the outcomes with similarly matched patients, patients who had similar comorbidities.

What are the key findings?

What we found was that number one, repeat TAVR procedure was feasible. So, you were able to do this procedure rather safely with low intra procedural outcomes.
For example, the risk of coronary obstruction was low 0.3%. The risk of converting a TAVR procedure into open heart surgery was also low, it was about 0.5%.

So I think these were one of the most feared complications. For example, coronary occlusion was a feared complication of redo TAVR procedure, but nonetheless that did not seem to be the case, at least in terms of intra procedural outcomes.
We further looked at the mortality and stroke at 30 days and at one year. And what we found was that the risk of death and risk of stroke was very similar between patients who had redo TAVR and patients who had TAVR for the first time. Or I should qualify patients who had TAVR for the first time who were matched with similar comorbidities and similar outcomes at one year.
So, I think that these data were reassuring in terms of the feasibility and the safety of the redo TAVR procedure with the balloon expandable valve.
I must emphasise that this analysis was done only for redo TAVR with the balloon expandable valve of the Sapien family.

Results in Perspective

One of the other things that I want to also talk about is we wanted to see if the outcomes differed on the timing of the redo TAVR procedure because TAVR failure might be either because the valve leaflets have degenerated, or it might be because of other reasons such as paravalvular aortic regurgitation.
Paravalvular aortic regurgitation patients would tend to present earlier while the valve degeneration, true valve degeneration would tend to present later on after the first procedure. We did analysis looking at early redo TAVR versus late redo TAVR based on the cut-off of one year and we found no differences in outcomes whether the redo TAVR was done earlier or later with a cut-off time point of one year. We also wanted to see if the initial valve affected the outcomes of the redo TAVR procedure with a balloon expandable valve. So, of the 1300 patients, 500 patients approximately had the balloon expandable valve as the initial valve and the other 800 patients had a self-expanding valve as their initial valve.
And what we found was that irrespective of the index valve at the time of the first TAVR procedure, there were no differences in terms of outcomes of death and stroke.
We also looked at the initial surgical risk. We divided these patients into STS scores; patients who were low risk for surgery or intermediate risk for surgery or high risk for surgery.
And what we found was that as the risk score increased, as the comorbidities increased, the mortality rates actually increased. And this was important for us to do because we wanted to put the results in perspective. The 30-day mortality of the overall cohort of redo TAVR patients was 4.7%. But then when you look at these patients and look at low risk patients where the STS score or the predicted risk of mortality was less than IV, the actual 30-day mortality was only 0.7%.
These were sicker patients. They were more often done in an emergency fashion compared to the first time TAVR patients and hence their mortality was 4.7% rather than the typical mortality of 1% to 2% that we are used to. It was important for us to establish that the outcomes depend upon what the baseline surgical risk was.
And then finally, I think the important thing to also talk about is the hemodynamics.
Because what we want to know is what are the hemodynamics after you do the redo TAVR? So, the numbers were reasonable, the rates of paravalvular or valvular regurgitation were similar and they were low with redo TAVR and native TAVR.

So I think the redo TAVR procedure was effective in treating the dysfunction of the failure of the failed valve, whether it was leakage, whether it was stenosis and the gradients, I have to say they were a little bit higher.
They were about two millimetres higher in patients who had redo TAVR procedure compared to patients who had TAVR for the first time, or one out of five patients had a gradient that was more than 20 millimetres of mercury.
So I think these gradients were higher immediately post procedure, but they were stable up to a year. We'll have to see what happens to these gradients and valve durability over a period of long term follow up, so I think that's something that we'll have to wait and watch for.

What are the next steps?

I think redo TAVR is a very important area of research, and we are going to need data from large registries such as this one, because this data was in all consecutive patients, but large data might often lack some granularity.
So, we will need a number of small registries as well, where we are actually collecting technical details about these procedures which will help us establish as to precisely what are the best patients to undergo redo TAVR procedure versus patients who might actually benefit more by having surgical explant of the valve and then having a surgical aortic valve replacement.