ACC 22: ADAPT-TAVR Shows SLT Does Not Affect CO for Patients After TAVR

- My name is Duk-Woo Park, DW Park, from the Asan Medical Centre. So I'm going to very happy to discuss our ADAPT-TAVR trial, will be presented at ACC 2022, late-breaking clinical trial.

Rationale of the Trial

Yes, so, and our ADAPT-TAVR trial has a very important study hypothesis. You know, on the basis of current available data and the subclinical leaflet thrombosis after TAVR is a really issue in daily TAVR practise.
So what is known, what is unknown? Usually we know the leaflet thrombosis, and that if you're going to use the oral anticoagulation rather than the antiplatelet therapy, and the significantly reduced overall instance of leaflet thrombosis. However, we don't know real the causal relationship of leaflet thrombosis and the cerebral thromboembolism.
Also, we don't know in that if you're going to use the oral anticoagulation rather than antiplatelet therapy, the OAC can reduce the leaflet thrombosis associate the cerebral thromboembolism or stroke or TIA.

Study Design, Endpoints and Patient Population

Our study is just targeting the TAVR recipient and the patient who underwent successful TAVR procedure, also without any clinical indication for long-term use of oral anticoagulation, such as HR fibrillation.
So, and we include 220 patients. In the randomization, one arm is edoxaban, 60 or 30 milligramme once daily, versus the other arm is dual antiplatelet therapy, aspirin plus Clopidogrel. When we enrol the patient at the time, the aspirin plus clopidogrel was default the recommendation strategy.
So our trial include nearly 220 patient, and we defined the primary clinical endpoint at six months a CT scan redefine the overall instance of leaflet thrombosis between two group. Also key secondary endpoint, we measure the serial MRI at baseline and six months follow up. Also, we measure the neurological and the neurocognitive function test at baseline and six months. Also, we measured echocardiographic parameter and any clinical event, bleeding, or the ischemic event between two groups.

Key Results

So our key result is very interesting, and the primary endpoint of leaflet thrombosis and the edoxaban group at six months occurred 9.8%. And the dual therapy group, DAPT group, occurred 18.4%. ITT population P value was 0.076. So we did not achieve the statistical significance. And PP pop protocol analysis, edoxaban group leaflet thrombosis instance 9.1% and DAPT group 19.1%. And the P value was 0.047 in PP population.
We achieved the statistical significance. The key secondary endpoint and the reevaluated MRI, serial MRI finding, and between two group the presence of a new cerebral lesion on MRI and occurred 25% in edoxaban group.
In DAPT group is 20.2% in DAPT group. We didn't find any difference the new MRI lesion. Also, we did not find any difference overall number of total new lesion over volume of total new lesion, although we achieved some significant reduction of over leaflet thrombosis with

edoxaban rather than DAPT therapy, and the leaflet new cerebral lesion on MRI, absolutely no difference at all.
Also we measure the neurological and neurocognitive function between two group, and the worsening of NHISS scale. This is a conventional neurological endpoint. Also worsening of modified Rankin scale and worsening of a Montreal Cognitive Assessment, absolutely no difference between two group.
Also another key finding, we did not find any causal relationship, any significant association, between the HALT and the leaflet thrombosis severity and the new lesion on brain MRI, we did not find any causal association.
Also, we did not find any association in the leaflet thrombosis severity and the neurological assessment outcome like NHISS, modified Rankin scale, and Montreal Cognitive dysfunction.

Impact on Research and Practice

I think our trial has a very important clinical implication in daily TAVR practise. And first, leaflet thrombosis has not been proven to affect clinical outcome for TAVR patient. And therefore, this imaging phenomenon should not dictate antithrombotic therapy for its prevention after TAVR. And second, the absence of evidence of temporarily related adverse clinical sequelae of imaging-detected subclinical leaflet thrombosis absolutely does not support routine imaging screening tests for detection of this phenomenon.
Also, imaging-guided antithrombotic strategy in case without hemodynamic or clinical significance should not be recommended.

Take-home Messages

Yeah, I think it's the take-home message: You know, we found some class effect if you're going to use the oral anticoagulation like edoxaban, our previous study, rivaroxaban, also the ATLANTIS apixaban shows the overall instance of leaflet thrombosis. However, we did not find, although we achieve the lower instance of leaflet thrombosis with oral anticoagulation instead of antiplatelet therapy, it does not associate any reduction of the thromboembolism on MRI and any change of neurocognitive dysfunction. So our finding absolutely support, then, the current guideline, updated guideline in European guideline and US guideline, and the patient without any indication of the oral anticoagulation, the single antiplatelet therapy, or aspirin monotherapy should be the choice of treatment at the TAVR procedure.