

## New data clarify leaflet thickening in TAVI and surgical aortic prostheses

May 21 2015

New data released today at EuroPCR 2015 suggest that thickening of the valve leaflets following implantation of a transcatheter or surgical aortic valve bioprosthesis is relatively rare, not linked to short-term clinical events, and not unique to any one type of valve. Longer-term follow-up and larger studies looking specifically at this issue are warranted, experts said here at a special session devoted to the emerging understanding of the phenomenon.

"At the present time, there is no evidence to support a change in patient selection, procedural aspects, or post-procedural management for transcatheter aortic valve implantation (TAVI) or surgical aortic valve replacement (SAVR)," said Dr. Lars Søndergaard of Rigshospitalet, Denmark, who led one of the leaflet studies. "But the findings call for further studies."

Well over 100,000 transcatheter <u>aortic valve</u> implantation procedures have been performed worldwide, making the minimally invasive procedure a standard therapy for patients with inoperable <u>severe aortic stenosis</u>, as well as for high-risk patients who are eligible for conventional surgery. In September 2014, imaging studies used in a US-based trial of a TAVI device identified thickening and reduced mobility of the device leaflet following implantation, prompting concerns that this phenomenon could have adverse clinical effects for the valve recipients. As a precaution, the trial was paused.

"In the short term we have not seen clinical consequences such as



strokes, but larger and longer term studies are needed," said Dr. Raj Makkar, associate director at Cedars Sinai Heart Institute, and author of another featured study. "These imaging findings should be looked at in the context of robust clinical trial data that is available on the efficacy of TAVI and SAVR."

During today's session, researchers presented results from three separate, single-centre studies providing insights from a total of 345 patients treated with a range of transcatheter or surgical valves. Among the insights:

- CT and echocardiographic imaging at 5 days, 30 days, or at later time points, depending on the study, found a spectrum of abnormalities including hypo-attenuated leaflet thickening, impaired leaflet motion, and thin films or small aggregations believed to be thrombus, in 7-15% of patients.
- Abnormalities detected on imaging were not unique to a particular surgical or transcatheter valve.
- Leaflet abnormalities were not associated with clinical events (stroke, systemic embolism, or valve failure), although follow-up, so far, has been short.
- Most advanced abnormalities resolved with the use of oral anticoagulants, although patient selection, anticoagulant type, and anticoagulant dose have not been established.

"The findings remind us that evidence is lacking for the current focus on antiplatelet therapy for newly implanted aortic bioprotheses," said Dr. Franz-Josef Neumann, medical director for the Department of Cardiology and Angiology II, University Heart Center Freiburg, Bad Krozingen, and lead author on the third study. "Nevertheless, it may be difficult to make advances, given the low level of risk that we have achieved already."



Dr. Bernard Prendergast, session co-chair and co-director of PCR London Valves as well as director of the Cardiac Structural Intervention Programme at Guys and St Thomas' Trust in London, UK, commented "TAVI is an established life saving procedure with a wealth of high quality clinical evidence demonstrating its safety, durability and effectiveness. The reassuring data presented today indicate that there is no need for clinicians to adjust their practice in relation to patient selection, performance of the TAVI procedure, or follow up protocols, including post-procedural imaging and anti-thrombotic therapy."

**More information:** Associated EuroPCR 2015 Session: Breaking news: leaflet thickening and reduced motion of biosprosthetic aortic valves, 8:15-9:50 CEST, Thursday May 21, Main Arena

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