Medical Xpress

Retrievable transcatheter aortic valve effective and safe in real world setting

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A retrievable and repositionable transcatheter aortic valve is effective and safe in a real world setting, according to research presented at ESC Congress 2014 today by Dr Stylianos Pyxaras from Germany. The direct flow medical (DFM) transcatheter aortic valve has unique features that improve operator control and has the potential to improve transcatheter aortic valve implantation (TAVI) outcomes in patients with severe aortic stenosis.

Dr Pyxaras said: "TAVI is well established as a percutaneous treatment option in patients with severe aortic stenosis, in whom surgery carries a high risk and is often prohibited."

He added: "The DFM prosthesis can be retrieved and repositioned before permanent implantation and allows enhanced control during the implantation procedure. The CE mark DISCOVER study previously showed high efficacy and safety rates of the DFM valve in patients with severe aortic stenosis (1), but until now this experience had not been confirmed in a real world setting."

The current study assessed early safety and device success in an international, multicentre prospective registry. Patients had severe aortic stenosis and were defined as high risk using the EuroSCORE (2). All patients underwent TAVI with the DFM valve. The findings were compared with the DISCOVER trial population results.

The study prospectively enrolled 105 patients. The study's primary

endpoint of all-cause mortality at 30 days was observed in only two patients (1.9%). Success of the device, as defined by the VARC-2 criteria (3), was similar in the real world experience when compared to the DISCOVER trial population (98.1% versus 93.3%, respectively; p=0.103). Major vascular complications that required the intervention of the vascular surgeon were observed in 3 cases.

The combined patient safety event endpoint was similar between the two cohorts (89.5% in the current trial versus 91.0% in DISCOVER; p=0.333). Ten patients (9.5%) underwent permanent pacemaker implantation due to post-procedural persistent advanced atrio-ventricular block compared to 17% in the DISCOVER trial (p=0.148). The observed rate of residual moderate aortic regurgitation was very low in the current patient population at 1.9%.

Dr Pyxaras said: "We observed – for the first time in a real world setting – high device success and early safety rates with the DFM prosthesis. The observed trend towards a higher device success rate compared to DISCOVER could be because cardiologists had more experience with the technique, since some of the centres in our study also participated in the CE mark trial."

He added: "The device has two unique features – it can be retrieved and repositioned. These characteristics guarantee enhanced control during positioning and may be responsible for the low rates of post implantation aortic regurgitation."

Dr Pyxaras concluded: "Our study investigated the impact of the DFM device on a pre-specified exploratory endpoint and the findings are based on a small number of events. The results suggest that the DFM valve appears to be a valuable addition to conventional TAVI methods in patients with severe aortic stenosis. However, our results are only hypothesis generating and should be confirmed in larger, randomised

trials."

More information: References:

(1) Schofer J, Colombo A, Klugmann S, Fajadet J, DeMarco F, Tchétché D, Maisano F, Bruschi G, Latib A, Bijuklic K, Weissman N, Low R, Thomas M, Young C, Redwood S, Mullen M, Yap J, Grube E, Nickenig G, Sinning JM, Hauptmann KE, Friedrich I, Lauterbach M, Schmoeckel M, Davidson C, Lefevre T. Prospective multicenter evaluation of the direct flow medical transcatheter aortic valve. J Am Coll Cardiol. 2014; 63(8):763-768. DOI: 10.1016/j.jacc.2013.10.013. Epub 2013 Nov 6.

(2) EuroSCORE is a method of calculating predicted operative mortality for patients undergoing cardiac surgery.

(3) The Valve Academic Research Consortium (VARC)-2 initiative provides standard definitions of TAVI clinical endpoints for use in clinical trials.

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