An update from the Medtronic CoreValve® Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) Trial: comparing CoreValve with surgical aortic replacement in intermediate risk patients

Transcatheter aortic valve implantation (TAVI) is a minimally invasive technique designed to treat malfunctioning heart valves by implantation of a heart valve bioprosthesis via a catheter, eliminating the need for open-heart surgery, cardiac arrest and the need for cardiopulmonary bypass. The CoreValve System (Medtronic, Inc.) has been shown to provide clinical and haemodynamic benefits during long-term follow-up for patients with symptomatic, severe aortic stenosis who are at high risk, or are ineligible, for open-heart surgery.[1,2]

At present, surgical aortic valve replacement (SAVR) is considered the gold standard for treatment of patients with symptomatic, severe aortic stenosis who are at low or intermediate surgical risk as estimated by the logistic EuroSCORE or Society of Thoracic Surgeons' (STS) score. This is reflected in the guideline recommendations of the European Society of Cardiology[3] and the American Heart Association/American College of Cardiology.[4] Subsequently, clinical data about the effectiveness of TAVI have been limited to those patients in whom surgery is not an option or those with a very high risk of surgical complications, for example patients with multiple comorbidities. However, as TAVI has been shown to be non-inferior in terms of mortality compared with SAVR among these patients,[5,6] it is a logical question whether the spectrum of patients potentially eligible for TAVI also extends to patients at lower risk.

The Medtronic CoreValve Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI; ClinicalTrials.gov identifier NCT01586910) trial will evaluate the potential for CoreValve to be considered for intermediate-risk patients who would typically be treated with open-heart SAVR.

SURTAVI is the largest global, randomized, controlled TAVI trial to date. Approximately 2,500 patients will be enrolled at up to 75 clinical worldwide sites, and will be treated by experienced heart teams that include interventional cardiologists and cardiac surgeons. Patients considered for the trial include those with severe, symptomatic aortic stenosis who are classified as intermediate surgical risk, defined by an STS mortality risk of ≥4% and ≤10%. Patients will be randomized equally to either TAVI with CoreValve or to surgery; CoreValve implantation will be performed by transfemoral, subclavian or direct aortic access, depending on the needs of the patient. Follow-up will be for five years.

The trial will evaluate whether the CoreValve System is non-inferior to surgical valve replacement, based on the composite primary endpoint of all-cause mortality and disabling stroke at 24 months. The first patient in the SURTAVI trial was treated at Rigshospitalet Copenhagen University Hospital in Copenhagen, Denmark on 18 July 2012.

The SURTAVI Trial at a glance

Sample size

- Approximately 2,500 patients with severe, symptomatic aortic stenosis who are classified as intermediate surgical risk (STS score ≥4% and ≤10%)

Study sites

- Up to 75 clinical sites, worldwide

Primary outcome

- All-cause mortality or disabling stroke (time frame: 24 months)

Secondary outcomes

- Device success: procedural success, hemodynamic performance, valve function
- TAVI vs SAVR: non-inferior outcomes in major safety and efficacy categories (Major Adverse Cardiovascular and Cerebrovascular Event [MACCE], Major Adverse Events [MAE], hemodynamics, functional status) as well as hospitalization rates and changes in quality of life

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