

Research Highlights

Highlights from the latest research in interventional cardiology



Remote monitoring of implantable cardiac defibrillators may be associated with reduced mortality in patients

Evaluation of: Saxon L, Hayes D, Gilliam R *et al.*: Long-term outcome after ICD and CRT implantation and influence of remote device follow-up: the ALTITUDE Survival study. *Circulation* 122, 2359–2367 (2010).

The LATITUDE remote monitoring system for implantable cardiac defibrillator (ICD) and cardiac resynchronization therapy defibrillator (CRT-D) devices was released in 2006 by Boston Scientific. This enabled patients to upload data from their devices from their home periodically, or on demand, via telephone line to a website managed by Boston Scientific. All devices implanted after 2004 that had remote capability could take advantage of the LATITUDE system. The decision to participate in the remote network is made by the implanting physician at the time of implantation or at the first post-implantation clinic follow-up. Saxon *et al.* present findings from the ALTITUDE project, a scientific initiative to analyze data collected from devices in the LATITUDE system.

Included in the study are data from 194,006 implanted devices, 69,556 of which were followed on the network and 124,450 only in the clinic. Data from a total of 2096 clinics in the USA were included. Patients from clinics that refused to participate and those with

no social security numbers, for which survival status from the Social Security Death Index could not be obtained, were excluded from the study.

Survival for all patients at 5 years was 68% for ICD and 54% for CRT-D patients. Compared with a matched cohort, patients in the network had a 50% relative risk reduction in mortality (hazard ratio of 0.56 for ICD and 0.45 for CRT-D). The number of shocks was no different between the two groups. In both groups a greater number of delivered ICD shock treatments was associated with increased mortality.

Because of mortality risk factors mismatch between the groups, a sensitivity analysis was performed, demonstrating that the risk factor burden in the non-network group would need to be five times that of the network group to reproduce the mortality difference observed in the study. This observation strengthens the association of reduced mortality in the network group. However, from this observational study we cannot attribute the mortality reduction in mortality to a single factor. Selection bias may play a role; physicians who are more engaged in care of their patients may have pushed for networking, and patients who preferred to be on the network may be more proactive in their care. It remains for future studies to establish whether these data can be efficiently processed and organized to aid the healthcare providers in making clinical decisions.

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Transcatheter aortic valve implantation: results from a large European center

Evaluation of: Godino C, Maisano F, Montorfano M *et al.*: Outcomes after transcatheter aortic valve implantation with both edwards-SAPIEN and CoreValve devices in a single center: the Milan experience. *J. Am. Coll. Cardiol. Int.* 3, 1110–1121 (2010).

One of the most exciting stories of the past year in interventional cardiology was the growth of transcatheter aortic valve implantation (TAVI). Although still pending US FDA approval, TAVI is rapidly becoming the standard of care in the treatment of patients with severe symptomatic aortic stenosis (AS) and a mortality risk prohibitive for surgical aortic valve replacement. The European experience provides the most data thus far, mainly in the form of large post CE mark registries. The SOURCE registry includes patients undergoing transfemoral or transapical implantation of the Edwards-SAPIEN Transcatheter Heart Valve (ESV; Edwards Life-Sciences, CA, USA). Overall survival in this registry is 91.5% at 30 days [1], and 76.1% at 1 year [2]. Similar results are found for the Medtronic CoreValve (MCV; Medtronic, MN, USA) [2]. The largest prospective randomized trial including mostly US sites is the recently published data from cohort b of the PARTNER trial, in which high-risk AS patients were randomized to medical therapy, including aortic balloon valvuloplasty, versus TAVI with the ESV. The overall survival rate of patients undergoing TAVI was approximately 70% compared with 50% in the medical therapy group [3].

Godino *et al.* conducted a prospective study of 137 consecutive AS patients undergoing TAVI at a single center, the San Raffael Institute, Milan, Italy [4]. Selected patients had symptomatic AS with a valve area less than 1.0 cm². Patients were classified as high risk

estimated by a EuroSCORE $\geq 20\%$ or STS score $\geq 10\%$. Also included were other risk factors for surgical mortality, such as prior thoracic radiotherapy, prior coronary artery bypass graft with patent grafts (particularly those that may be subject to damage with sternotomy), porcelain aorta, liver cirrhosis or a high degree of patient frailty. Patients were evaluated by two interventional cardiologists, a cardiac surgeon and an anesthesiologist for inclusion in the study.

Patients were selected to undergo placement of an ESV or MCV via a transfemoral, transaxillary or transapical approach. A transfemoral placement of ESV or MCV, depending on the size of the aortic annulus and ileo-femoral vessels, was preferred if the ileo-femoral vessels were greater than 6 mm in diameter. Patients with ileo-femoral vessels less than 6 mm in diameter underwent transaxillary TAVI if the axillary vessel was 6 mm or greater. Patients without sufficiently large vessels received transapical ESV placement. Procedural, 30-day and 6-month outcomes were reported.

Transcatheter aortic valve implantation was performed on a total of 137 patients. Of the 79 patients undergoing ESV, 61 were placed via the transfemoral route, 15 transapically and three via a transaxillary route. Out of 58 patients receiving MCV, 46 underwent a transfemoral procedure and 12 were placed via a transaxillary approach. For the majority of patients undergoing a transfemoral approach, the procedural success rate was high for both the ESV (98.4%) and the MCV (89%) with no procedural deaths. Two out of 15 transapical and one out of 15 transaxillary procedures resulted in procedural failure. Major vascular complications, including vessel rupture, aortic dissection, limb-threatening ischemia or bleeding requiring surgical or percutaneous correction occurred in 20.6%



of patients undergoing a transfemoral approach (21.3% with ESV and 19.6% with MCV). Procedural stroke rate was low, with one event in a patient receiving ESV. The need for a permanent pacemaker was 26.1 and 11.5% for the MCV and ESV groups, respectively. One mortality was reported at 30 days in a patient who received a MCV, and all-cause mortality at 6 months was 12.2% (8.3% with ESV and 18.4% with MCV). In the transapical group, death occurred in four out of 15 patients (26.6%). Major adverse cardiac and cerebrovascular event rates were 16.7% with ESV and 28.9% with MCV at 6 months. These data add to the growing evidence that TAVI may be performed with excellent procedural success and mortality rates that compare favorably with surgery in high-risk symptomatic AS patients [5]. Further advances in delivery systems, including reduction of sheath size and innovation in prosthetic valve design, will broaden the use of TAVI in higher risk individuals in the coming years.

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The Medtronic Engager valve: a transapical implantable valve

Evaluation of: Falk V, Walther T, Schwammenthal E: Transapical aortic valve implantation with a self-expanding anatomically oriented valve. *Eur. Heart J.* 32(7), 878–887 (2011).

The initial experience with transcatheter aortic valve implantation was with a balloon expandable system, leading to the balloon expandable Edwards-SAPIEN Transcatheter Heart Valve (ESV; Edwards Life-Sciences, CA, USA), which is now available to the consumer market in Europe. The self-expanding Medtronic CoreValve (MCV; Medtronic, MN, USA) followed the ESV to market, while both are still for investigational use in the USA. Technology is rapidly being developed to downsize delivery systems and increase prosthesis options to expand use to ever more high-risk patients with increasingly complex aortic annulus anatomy.

The Medtronic Engager valve (Medtronic, MN, USA) is an investigational self-expanding bovine prosthesis with a transapical delivery system designed to facilitate anatomical positioning. The valve consists of bovine pericardium mounted on a self-expanding nitinol frame. The valve is produced in a single 23-mm size to fit aortic annuli of 19–23 mm. The valve is shaped to have an inlet diameter of 28 mm, a waist diameter of 18 mm and a diameter of 23 mm at the outlet. Via a transapical approach, balloon valvuloplasty is performed prior to positioning the valve via a 30F introducer sheath.

A first-in-human investigation of the Medtronic Engager valve was conducted by Falk *et al.* [1]. Between June 2008 and October 2009 in three German centers, a total of 30 elderly patients >75 years of age were selected. Included patients had severe symptomatic aortic stenosis, with



a valve area less than 0.8 cm², a mean gradient of greater than 40 mmHg and an aortic annulus diameter of between 19 and 23 mm. High surgical risk was determined by a EuroSCORE greater than 11%. Congenital bicuspid valves, those with fused commissures, and eccentrically calcified valves were excluded, along with patients having severe left ventricular dysfunction or a life expectancy of <12 months. Primary end points were device success – defined as stable device placement and adequate function as assessed by angiography and echocardiography immediately post-procedure – and major adverse cardiac and cerebrovascular events, a composite of any death, myocardial infarction or disabling stroke at 30 days post-procedure.

The mean age of the 30 enrolled patients was 83.4 years with 83% of patients being female. The mean EuroSCORE was 23.4. The device was placed accurately in 29 of the 30 patients. Mean aortic pressure gradient was 12.6 mmHg by echo Doppler post valve implantation. No patients had greater than grade II aortic insufficiency. Permanent pacemaker implantation was required in three patients (10%), and aortic dissection was noted in 13% of patients. The mortality rate at 30 days was 20%, while survival at 6 months was 56.7%.

Although this valve was implanted successfully in all but one of the study patients, and 30-day mortality is in line with that seen with the ESV in the SOURCE registry [2], there remains concern over the high rate of complications. Owing to the high incidence of aortic dissection, the delivery system is undergoing re-engineering. The high rate of permanent pacemaker requirement is likely due to the fact that compression of the conduction system is not unique to this self-expanding valve, and is documented to be as high as 40% with the MCV [3]. Further refinement and investigation of this system will be required before it may be considered an option alongside the successful ESV and MCV currently on the market.

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