Valvular Heart Disease – From Clinic to Catheter Strategies

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Assessing Risk

Blase A. Carabello, MD, Baylor College of Medicine, Houston, Texas, USA, discussed variables that put patients who are undergoing aortic valve replacement at increased risk (eg, coronary heart disease, renal failure, liver and lung disease, and porcelain aorta); the impact of these factors on morbidity and mortality; and the validity of standardized risk algorithms.

The European System for Cardiac Operative Evaluation (EuroSCORE) [http://www.euroscore.org/] and the Society of Thoracic Surgeons (STS) score [http://www.sts.org/quality-research-patient-safety/quality/quality-performance-measures] [Roqes F et al. *Eur Heart J* 2003; Edwards FH et al. *Ann Thorac Surg* 1997] are used widely for the evaluation of procedural risk in cardiac surgery [http://209.220.160.181/STSWebRiskCalc261/de.aspx].

Dr. Carabello discussed bias in the STS database (weighted toward coronary artery bypass grafting) and recent modifications in its scoring system for valvular heart disease. Risk factors not only include renal and lung function, number of surgeries, and whether the patient has coronary artery disease but also a host of unmeasured variables, such as frailty, depression, the clinician's overall impression, and the success rate of the team that is selected to perform the operation.

In that noncardiac comorbidities can outweigh risks that are associated with cardiac issues and that all risk is individual, it is in the patient's best interests to have his or her case reviewed by a joint cardiology-cardiac surgery team to determine which therapy is best for each patient.

Aortic Valve Technology

Technological advances in aortic valves, delivery systems, and techniques have improved outcomes, reduced length of hospital stays, and confirmed all preclinical expectations in an increasingly broad spectrum of patients. A presentation by Helene Eltchaninoff, MD, Charles Nicolle Hospital, Rouen, France, reviewed aortic valve technology.

Dr. Eltchaninoff discussed transcatheter aortic valve implantation (TAVI) valves, delivery systems, and techniques from Edwards Lifesciences since 2004, comparing the company's earlier SAPIEN™ transfemoral and transapical 23- and 26-mm valves with the RetroFlex delivery system to its SAPIEN XT™, which is currently being used in Europe with improved Novaflex transfemoral and Ascendra 2 transapical delivery systems.

There are approximately 500 TAVI centers in Europe and some 50,000 patients worldwide. Expanded clinical indications will be determined by improvements in transcatheter valves and delivery systems, new imaging technologies and embolic protection devices, upcoming registries, controlled trials in specific subsets of patients, and assessment of valve and platform durability.

Outcomes of TAVI in high-risk and inoperable patients have been reported in a number of registries and have confirmed the results of the pivotal PARTNER-US Trial. TAVI has recently been approved by the United States Food and Drug Administration for use in nonsurgical patients. Patients must enroll and be followed long term within the new STS/ACC TVT Registry [https://www.ncdr.com/TVT/Home/Default.aspx].

Mitral Valve Technology

Donald D. Glower, MD, Duke University Medical Center, Durham, North Carolina, USA, discussed the evolution of mitral valve technology—from closed commissurotomy in 1948 to percutaneous replacement in 2010.

Better imaging and advances in robotic technology have improved patient appeal and advanced the standard of care. In imaging, 3- and 4-dimensional ultrasonographic capabilities have overcome limitations of current methods with automatic modeling, semiautomatic generation of the location of the mitral annulus, and improved visualization and understanding of mitral valve behavior [Schneider RJ et al. *Med Image Comput Comput Assist Interv* 2011].

In Europe and the United States [Casselman FP et al. *Circulation* 2007], less-invasive procedures include mitral valve repair under direct vision through a right minithoracotomy [Seeburger J et al. *Eur J Cardiothorac Surg* 2008] and a total endoscopic approach through a 3–4-cm incision [Casselman FP et al. *Circulation* 2003]. These techniques compete with the robotic approach, and currently, there is no indication that the robotic technique is any better or worse than the others or that it is more reproducible [Trento A. *Mayo Clin Proc* 2011].

Future mitral valve technology will likely be less invasive, attract new patients, have increased initial costs, be directed toward higher-risk patients, and have a longer learning curve.

Decision-Making in Patients With Advanced Valvular Disease

Robert O. Bonow, MD, Northwestern University Feinberg School of Medicine, Chicago, Illinois, USA, discussed factors that weigh into decision-making in the treatment of advanced valve disease with aortic stenosis (AS) and mitral regurgitation (MR).

Exercise testing can help identify patients who might benefit from early valve repair or replacement. In addition, stress echocardiography has emerged as an important component of stress testing in patients with valvular heart disease [Picano E et al. *J Am Coll Cardiol* 2009].

In challenging patients with MR, new data show that correction with the MitraClip in nonresponders to cardiac resynchronization therapy improves symptoms and promotes reverse remodeling [Auricchio A et al. *J Am Coll Cardiol* 2011].

The PARTNER Trial [NCT00530894] indicated that in high-risk patients with severe AS, transcatheter and surgical procedures for aortic valve replacement are associated with similar rates of survival at 1 year, although there were important differences in periprocedural risks [Smith CR et al. *N Engl J Med* 2011].

The rates of death from any cause were 3.4% in the transcatheter group and 6.5% in the surgical group at 30 days (p=0.07) and 24.2% and 26.8%, respectively, at 1 year (p=0.44), with a reduction of 2.6 percentage points in the transcatheter group (upper limit of the 95% CI, 3.0 percentage points; predefined margin, 7.5 percentage points; p=0.001 for noninferiority). The rates of major stroke were 3.8% in the transcatheter group and 2.1% in the surgical group at 30 days (p=0.20) and 5.1% and 2.4%, respectively, at 1 year (p=0.07).

At 30 days, major vascular complications were significantly more frequent with transcatheter replacement (11.0% vs 3.2%; p<0.001); adverse events that were more frequent after surgical replacement included major bleeding (9.3% vs 19.5%; p<0.001) and new-onset atrial fibrillation (8.6% vs 16.0%; p=0.006). More patients who were undergoing transcatheter replacement had an improvement in symptoms at 30 days, but by 1 year, there was no significant between-group difference.

In severely ill patients with AS who were considered to be at too high a risk for surgical aortic valve replacement (SAVR), the PARTNER B Study showed that TAVI, compared with standard therapy, significantly reduced the rates of death from any cause (30.7% vs 50.7%; HR, 0.55; 95% CI, 0.40 to 0.74; p<0.001) and repeat hospitalization and cardiac symptoms (42.5% vs 71.6%; HR, 0.46; 95% CI, 0.35 to 0.59; p<0.001) [Leon MB et al. *N Engl J Med* 2010]. However, there was a higher incidence of major stroke (5.0% vs 1.1%; p=0.06) and major vascular events (16.2% vs 1.1%; p<0.001). Two-year follow-up data, recently reported at TCT in 2011, confirmed these earlier observations. see the peer-reviewed summary here: http://www.nxtbook.com/nxtbooks/md_conference_express/tct2011/#/0.

In patients with severe AS and depressed left ventricular systolic function (LVEF ≤50%), TAVI is associated with better LVEF recovery compared with SAVR [Clavel MA et al. *Circulation* 2010]. Long-term follow-up of this important surrogate outcome and the study of whether it remains an important predictor of clinical outcomes in TAVI patients are ongoing.

In advanced valve disease with aortic stenosis, TAVI represents a transformative technology with enormous potential, but its broad application also presents issues of patient selection, cost-effectiveness, and the need for dedicated, expert heart valve centers. For the majority of patients, SAVR represents the standard, with proven safety and durability. However, too many patients are not referred for surgery, and of those that are, the ones who are at highest risk should be treated at centers of excellence.