Highlights from the Transcatheter Cardiovascular Therapeutics Conference 2010: Washington, DC, September 21–25, 2010

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The Twenty-second Annual Transcatheter Cardiovascular Therapeutics (TCT) conference was held in Washington, DC, from September 21 to 25, 2010. Sponsored by the Cardiovascular Research Foundation, this is the largest interventional cardiovascular conference in the world with customized programs for interventional cardiologists, radiologists, cardiac surgeons, and vascular surgeons. With the exponential growth of catheter-based cardiac and vascular treatments, the relevance to and impact of the conference on the practice of cardiothoracic and vascular surgeons is ever increasing. The results of clinical trials presented at the conference that hold a specific interest for cardiac surgeons are the focus of this report.

TRANSCATHETER VALVE THERAPIES

Aortic Valve Replacement

Edwards SAPIEN valve (first generation with Ascendra delivery system [Edwards Lifesciences, Inc, Irvine, Calif]). Arguably the most high-profile clinical study presented at the TCT this year was the initial cohort of the landmark Placement of AoRTic TraNscathetER Valve (PARTNER) clinical trial. This represents the first US randomized percutaneous aortic valve trial. Two cohorts of patients were evaluated for the PARTNER trial: cohort A compared surgical aortic valve replacement versus transcatheter aortic valve implantation (TAVI) among high-risk operative candidates whereas cohort B examined outcomes in inoperable patients. The cohort B results were presented at TCT, whereas cohort A results were anticipated in April 2011. Cohort B randomized 358 patients with symptomatic, severe aortic stenosis not suitable for surgical therapy to either TAVI (n = 179) or standard medical therapy, including possible balloon valvuloplasty (n = 179).[1]

The primary end point of all-cause mortality at 1 year was significantly lower in the TAVI group than in the standard therapy group (30.7% vs 49.7%; $P < .001$) with a corresponding number-needed-to-treat to prevent 1 death of 5. Composite end points of all-cause mortality, repeat hospitalization, and stroke at 1 year were also significantly lower in the TAVI group (42.5% vs 71.6%; $P < .001$). The full report was recently published.[2]

Previous data from the Canadian Edwards TAVI Multicenter Registry of 339 patients receiving either transfemoral (TF) (n = 162) or transapical (TA) (n = 177) TAVI revealed that procedural mortality was similar (1.8% TF vs 1.7% TA) but significantly lower in the TF group when extended out to 30 days (9.9% vs 11.3%). New data from extended follow-up show that at 2 years, survival in both groups equalized at approximately 68%, and predictors of late mortality include chronic obstructive pulmonary disease, Society of Thoracic Surgeons score, chronic renal insufficiency, and periprocedural sepsis.[3]

The PARTNER-EU registry of 61 TF and 69 TA patients showed decreased mortality in the TF group (8% vs 19%) with survival curves continuing to diverge at 18 months in favor of the TF patients (29% TF mortality vs 57% TA mortality).[4]

Two cohorts from the SOURCE registry[5] were presented: the first consisting of 1123 patients enrolled between November 2007 and January 2009 from 32 centers; the second consisting of 1306 patients enrolled between February and December 2009 from 38 centers. TF patient mortality decreased from cohort 1 to cohort 2 whereas TA mortality remained stable in both cohorts at 30 days. It was noted that risk scores were lower in cohort 2, which may help explain the improved results. Mortality for both cohorts at 30 days was 7.5% in the TF group and 10.7% in the TA group.[5]

Walther[6] from Leipzig presented the outcomes of a large cohort of 357 TA TAVI patients. Thirty-day mortality was 8.1%, stroke 0.5%, and need for permanent pacemaker 4.5%. There was an 11% incidence of periprocedural complications that was associated with a 30% mortality. Survival at 1 and 2 years was 73% and 68%, respectively.

Webb[7] from Vancouver presented results of transcatheter valve replacement in patients with pre-existing stented valves (“valve-in-valve”). The cohort of 29 patients consisted of 13 with prosthetic mitral valves, 11 with prosthetic aortic valves, 3 with prosthetic pulmonic valves, and 2 with prosthetic tricuspid valves. Almost all valve replacements were performed via the TA approach with the exception of tricuspid valves, which were implanted through a transatrial approach. Note was made that the minimum size of the stented prosthetic valve was 23 mm to accommodate a SAPIEN valve and achieve acceptable gradients. Thirty-day mortality for this small cohort was 7%.

The COMPASSION-US trial[8] looked at 30 patients with previous tetralogy of Fallot repair or Ross procedure who

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Disclosures: Authors have nothing to disclose with regard to commercial support.

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J Thorac Cardiovasc Surg 2011;142:468-71
0022-5223/$36.00

doi:10.1016/j.jtcvs.2011.04.013

Abbreviations and Acronyms

MACCE = major adverse cardiovascular and cerebrovascular events
PARTNER = Placement of AoRTic TraNscathetER Valve clinical trial
TA = transapical
TAVI = transcatheter aortic valve implantation
TCT = Transcatheter Cardiovascular Therapeutics
TF = transfemoral

subsequently had pulmonary insufficiency with or without stenosis and were treated with transcatheter pulmonic SAPIEN valve implantation. The mean age of these patients was 31 years and survival at 1 year was 92.3%.

The preliminary results of the PREVAIL-EU[9] study of 150 patients who received TF TAVI using the new SAPIEN XT valve with the smaller 18F NovaFlex delivery device (Edwards Lifesciences) was presented. These patients had Society of Thoracic Surgery risk scores of greater than 10 or log EuroSCOREs of greater than 20. The first 93 patients had a mortality incidence of 8.6%, stroke incidence of 3.2%, and vascular complication incidence of 12.9%. Results for the full cohort of 150 patients should be available by fall of 2011.[9]

Medtronic CoreValve (Medtronic, Inc, Minneapolis, Minn). Preliminary results of 118 patients (375 planned) from 10 centers from the Australia–New Zealand Medtronic CoreValve Registry[10] revealed a 96% procedural success rate with 30-day incidences of mortality 5.6%, stroke 1.9%, and permanent pacemaker requirement 40%.

A safety and efficacy study of the next generation of the 18F Medtronic CoreValve also had its preliminary results reported for the first 88 patients. An 18% mortality at 30 days and 28% mortality at 1 year were reported.[11] Randomized controlled trials of TAVI using the 18F CoreValve have started in both Europe (SURTAVI)[12] and in the United States with the US Pivotal Trial[13] recently approved by the Food and Drug Administration.

New and upcoming TAVI devices. First-in-man safety and efficacy studies in small series of patients were presented for several new TAVI devices including the Direct Flow Medical percutaneous aortic valve (Direct Flow Medical, Inc, Santa Rosa, Calif), the Sadra Medical Lotus Valve System (Sadra Medical, Inc, Los Gatos, Calif), the Medtronic Ventor Engager transapical valve (Medtronic), the Jena transapical valve (JenaValve Technology GmbH, Munich, Germany), the Symetic Accurate transpical valve (Symetic Inc, Switzerland), and the Heart Leaflet Technologies system (Heart Leaflet Technologies, Inc, Maple Grove, Minn).

St Jude Medical, Inc (St Paul, Minn), unveiled its new transcatheter valves, which consist of both bovine and porcine pericardial valves on a nitinol self-expanding stent that will be repositionable and retrievable. There will be an 18F TF system and a 24F sheathless-design TA system. The TF system can be resheathed after up to 95% deployment of the valve. A European trial is planned for 2011 and a US trial for 2012-2113.[14]

Mitral Valve Repair

In contrast to the large clinical trial results from TAVI, adoption of transcatheter mitral repair technology has lagged. Nevertheless, trial updates for several transcatheter mitral technologies, including annuloplasty and edge-to-edge repair, were presented.

Coronary sinus annuloplasty devices. The EVOLUTION II prospective observational study/case series using the Edwards MONARC device reported preliminary results with 52 patients; device placement was planned for 34 of them and medical therapy for 18. Of the 34 patients in whom device placement was planned, 30 were successfully implanted with 30-day incidences of mortality of 3.3% and myocardial infarction 3.3%. Mortality at 6 months for device patients was 4.2%. The primary end point of 1 grade or more decrease in mitral regurgitation was successfully met in 92% of device patients. There were no device fractures or separations, but 1 death, 1 myocardial infarction, and 1 case of device migration. The MONARC program was discontinued owing to slow trial enrollment.[15]

Preliminary results from the TITAN study using the CDI Carillon, recapturable, nitinol, self-expanding anchor, coronary sinus annuloplasty device (Cardiac Dimensions, Inc, Kirkland, Wash) enrolled 65 patients of whom 53 qualified for device implantation. Thirty-six (68%) were successfully implanted, with the remainder not implanted owing to either coronary artery compromise (8/53) or failure to reduce mitral regurgitation (9/53). Follow-up at 30 days demonstrated a 1.9% death rate and a wireform fracture rate of 22%. Among those able to receive a device, there was a mean 40% reduction in quantitative measures of mitral regurgitation as well as reductions in NYHA class and improvements in left ventricular remodeling, which persisted at 1 year.[16]

Preliminary results from the PTOLEMY 2 study using the Viacor PTMA system (Viacor, Inc, Wilmington, Mass) of 37 patients; 33 had attempted implants, of which 27 (82%) were successful. Mortality in the implanted patients was 22.2% (6/27 patients).[17]

Direct annuloplasty devices and other concepts. Several devices were reported to have "first-in-man" safety and