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

Jack C. J. Sun, MD, MSc, Ravi K. Ghanta, MD, and Michael J. Davidson, MD

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 Multi-center 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 registry⁵ 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

Walther⁶ 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.

Webb⁷ 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 trial⁸ looked at 30 patients with previous tetralogy of Fallot repair or Ross procedure who

From the Division of Cardiac Surgery, Brigham & Women's Hospital Harvard Medical School, Boston, Mass.

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Address for reprints: Jack C. J. Sun, MD, MSc, Division of Cardiac Surgery, Brigham and Women's Hospital, 75 Francis St, Boston, MA 02115 (E-mail: [sunjc2@mcmaster.ca](mailto:sunjic2@mcmaster.ca)).

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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-EU⁹ 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 Registry¹⁰ 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 Trial¹³ 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 transapical valve (Symetic Inc, Switzerland), and the Heart Leaflet Technol-

ogies 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 2012–2013.¹⁴

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

feasibility studies underway including the Mitralign Direct Annuloplasty System (Mitralign, Inc, Tewksbury, Mass),¹⁸ the GDS Accucinch System (Guided Delivery Systems, Inc, Santa Clara, Calif),¹⁹ and the ReCor System (Ultrasound Therapy; ReCor Medical, Ronkonkoma, NY).²⁰

The MiCardia Adjustable Mitral Ring (MiCardia Corporation, Irvine, Calif) was presented as an investigational device, which is an annuloplasty ring that is inserted surgically. The ring itself contains electrodes attached to a lead that is placed subcutaneously and can be retrieved postoperatively so that radiofrequency energy can be applied, causing the ring to tighten.²¹

Another concept presented was the mitral spacer concept, whereby a balloon is implanted to the left ventricle, tethered to the apex, and provides additional coaptation surface between the mitral valve leaflets. This remains in preclinical testing.²²

Edge-to-edge repair. In the United States, the MitraClip device (Abbott Laboratories, Abbott Park, Ill) continues to be implanted as part of the REALISM continued access registry after the EVEREST II randomized clinical trial. Several subgroup analyses from EVEREST II were presented at TCT and this device remains in the forefront of current transcatheter mitral repair technologies, having achieved CE mark in Europe in March 2008. Glower²³ reported that surgery after failed MitraClip insertion was successful up to 5 years after the initial procedure and did not differ in safety or efficacy from those patients randomized to initial surgery. In addition, prior MitraClip insertion did not appear to predispose to a higher likelihood of valve replacement versus repair.

Mitral Valve Replacement

Still in its investigational stage, the ValveXchange device (ValveXchange, Inc, Aurora, Colo) is made up of 2 components: the Vitality valve (bovine pericardium) within the Vanguard base or stent. The valve can be implanted via a transapical, transcatheter technique, and the Vitality valve itself can be removed from the Vanguard base/stent and replaced with a new valve when needed.²⁴ Several other catheter-based mitral valve devices were presented, although all remain in preclinical testing.²⁵

CORONARY REVASCULARIZATION

The SYNTAX trial randomized 1800 patients with left main or 3-vessel coronary artery disease to either coronary artery bypass grafting or percutaneous coronary intervention. Three-year follow-up for the entire cohort was previously presented at the 2010 meeting of the European Association for Cardio-Thoracic Surgery. At TCT, subgroup analyses of patients with left main and 3-vessel coronary artery disease within the SYNTAX trial were presented. This showed no detectable difference between

coronary artery bypass grafting ($n = 348$) and percutaneous coronary intervention ($n = 357$) in patients with left main disease for the primary composite end point of major adverse cardiovascular and cerebrovascular events (MACCE) (22.3% vs 26.8%; $P = .2$) nor the secondary end points of death or myocardial infarction. There were significantly more strokes in the coronary bypass group (4.0% vs 1.2%; $P = .02$) and a higher incidence of repeat revascularization in the percutaneous coronary intervention group (11.7% vs 20.0%; $P < .01$).²⁶

In patients with 3-vessel coronary artery disease, coronary bypass grafting ($n = 897$) when compared with percutaneous coronary intervention ($n = 903$) reduced MACCE (18.8% vs 28.8%; $P < .01$), death (5.7% vs 9.5%; $P = .02$), myocardial infarction (3.3% vs 7.1%; $P < .01$), and need for repeat revascularization (10.0% vs 19.4%; $P < .01$) with no detectable difference in stroke (2.9% vs 2.6%; $P = .64$).²⁷

THORACIC AORTIC ENDOGRAFT

The use of thoracic endografts was discussed for a number of challenging clinical scenarios. Dake²⁸ presented evidence supporting the use of endografts for complicated type B dissection, traumatic disruption, and aortic rupture. A number of next-generation devices were discussed, including lower-profile 16F delivery systems, branched and fenestrated graft designs, dissection-specific designs, and ascending aortic devices.²⁹

CONCLUSIONS

Although TCT continues to be a conference largely attended by interventional cardiologists, its content is becoming increasingly relevant to cardiac surgeons. In particular, catheter-based valvular therapies are developing rapidly largely owing to strong interest and enthusiasm from industry, clinicians, and patients. The surgical presence and participation at TCT has increased in recent years and has been heralded by the initiation, in 2007, of a "TCT for Surgeons" section at the meeting. This focuses on relevant developments for the surgical community as well as on training for transcatheter techniques and is now cosponsored by The American Association for Thoracic Surgery. Undoubtedly, the relevance of the TCT content for cardiac surgeons will continue to grow with the growth of catheter-based therapies.

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