CONTINUING MEDICAL EDUCATION INFORMATION

The Society of Thoracic Surgeons is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The Society of Thoracic Surgeons designates this live activity for a maximum of 34.25 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity. The Late-Breaking Abstract component of the STS 51st Annual Meeting has been designated for a maximum of 1.0 AMA PRA Category 1 Credits™.

The American Board of Cardiovascular Perfusion designates this activity for 1.20 Category I CEUs.

Unless otherwise noted in this booklet or by the speakers, speakers have no commercial relationships to disclose and will be presenting information only on devices, products, or drugs that are FDA-approved for the purposes they are discussing.

Presenting authors are listed in bold on each abstract.
Late-Breaking Abstract Session: Adult Cardiac

Moderators: Craig H. Selzman, Salt Lake City, UT, and Richard J. Shemin, Los Angeles, CA

The physician competencies addressed in this session are patient care and medical knowledge. These physician competencies will be addressed through a series of individual lectures and a brief question-and-answer session after each topic.

4:15 PM

Early Hemodynamic Performance and Left Ventricular Mass Regression After Rapid Deployment Aortic Valve Replacement in 116 Patients: A Single-Center Experience

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La Timone Hospital, Marseille, France

COMMERCIAL RELATIONSHIPS  F. Collart: Consultant/Advisory Board, Edwards Lifesciences Corporation

REGULATORY DISCLOSURE  This presentation will address the Edwards Lifesciences Intuity Elite valve system, which has an FDA status of investigational.

Purpose: The development of left ventricular (LV) concentric hypertrophy in the natural course of aortic stenosis is known as an independent prognostic factor of morbidity and mortality. The regression of LV mass after Intuity rapid deployment bioprosthesis implantation is still unknown. We report the early results of a prospective single-center experience.

Methods: Enrolled patients received an Intuity bioprosthesis between July 2012 and July 2014. All patients received transthoracic echocardiography (TTE) pre- and postoperatively, and perioperative transesophageal echocardiography. After discharge, a prospective follow-up (FU) was proposed to all patients with visits at 1 month and 1 year. Each visit included a clinical exam and a TTE with specific assessment of left ventricular functioning and hemodynamic parameters. One month vs preoperative TTE data were compared using paired t-test or non-parametric Wilcoxon signed-rank test when appropriate.

Results: One hundred sixteen patients (78 males, mean age: 77 years ± 6.3 years, mean EuroSCORE II: 3.0% ± 2.5%) were enrolled. Forty-three patients (37.4%) were in NYHA III/IV and 88 (75%) had hypertension. The implantation was successful in all. Thirty-four patients (29%) had concomitant procedures. Bioprosthesis size was 19 mm and 21 mm in 66 patients (56%). For isolated aortic valve replacement, the mean x-ray computed tomography and cardiopulmonary bypass times were 37.7 min ± 12.8 min and 59.1 min ± 18.3 min, respectively. Significant improvements in TTE parameters were observed between preop and 1-month FU: aortic valve area (0.9 cm² ± 0.3 cm² vs 1.8 cm² ± 0.6 cm²; \( p < 0.001 \)); mean transaortic gradient (56 mm Hg ± 19 mm Hg vs 12 mm Hg ± 6 mm Hg; \( p < 0.001 \)), LV mass index (167 g/m² ± 45.1 g/m² vs 123 g/m² ± 25 g/m²; \( p = 0.002 \)), and relative wall thickness (0.6 ± 0.1 vs 0.55 ± 0.11; \( p < 0.001 \)). Only two patients (1.9%) had a paravalvular regurgitation > grade 1. Major bleeding was observed in 10 patients (8.8%), pacemaker was required in four patients (3.5%), and four patients (3.5%) had a neurologic event. No endocarditis or deaths were reported.
Conclusions: To date, this cohort is the largest single-center experience with the Intuity rapid deployment valve and shows favorable early clinical and echocardiographic outcomes in all cases. Data at 1 year will provide additional evidence regarding the potential benefits of the rapid deployment valve in the treatment of aortic stenosis.

Table 1: TTE characteristics of 116 patients operated on for severe aortic stenosis. Comparison between baseline and 1-month follow-up.

<table>
<thead>
<tr>
<th>TTE Data (n=116)</th>
<th>Baseline</th>
<th>1month FU</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>LVEF (%)</td>
<td>66 ± 6</td>
<td>62.2 ± 8.4</td>
<td>ns</td>
</tr>
<tr>
<td>Interventricular septum (mm)</td>
<td>14.9 ± 1.7</td>
<td>14 ± 2</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Posterior wall</td>
<td>15.3 ± 1.4</td>
<td>12.3 ± 1.5</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>LV End diastolic diameter (mm)</td>
<td>47.7 ± 6.6</td>
<td>45.7 ± 5.9</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>LV End systolic diameter (mm)</td>
<td>33.6 ± 6.8</td>
<td>32 ± 6.3</td>
<td>ns</td>
</tr>
<tr>
<td>LV End diastolic volume (mm)</td>
<td>131.5 ± 50.2</td>
<td>114 ± 41.3</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>LV End systolic volume (mm)</td>
<td>49.4 ± 33.2</td>
<td>45.9 ± 25.5</td>
<td>ns</td>
</tr>
<tr>
<td>LV mass (g/m²)</td>
<td>167 ± 45.1</td>
<td>123.3 ± 25</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>RWT</td>
<td>0.6 ± 0.1</td>
<td>0.5 ± 0.1</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Vmax (m/s)</td>
<td>4.6 ± 0.8</td>
<td>2.2 ± 0.4</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Aortic valve area (cm²)</td>
<td>0.8 ± 0.3</td>
<td>1.8 ± 0.6</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Aortic valve area index (cm²/m²)</td>
<td>0.5 ± 0.2</td>
<td>1 ± 0.3</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Mean trans aortic gradient (mmHg)</td>
<td>56.7 ± 19.3</td>
<td>12.4 ± 6.4</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Stroke volume index (ml/m²)</td>
<td>49.9 ± 11.6</td>
<td>41.9 ± 8.8</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Periprosthetic aortic regurgitation &gt;1(%)</td>
<td>-</td>
<td>2(1.9%)</td>
<td>-</td>
</tr>
<tr>
<td>sPAP (mmHg)</td>
<td>33.8 ± 13.8</td>
<td>30.3 ± 7.5</td>
<td>ns</td>
</tr>
</tbody>
</table>

LVEF = Left ventricular ejection fraction, LV = left ventricle, RWT = relative wall thickness (RWT = 2 x posterior wall/LVEDD), sPAP = systolic pulmonary arterial pressure
ABLATE Trial Mid-Term Results: Safety and Efficacy of Cox-Maze IV With a Novel Dual Bipolar Ablation Device

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¹Mid-Atlantic Cardiothoracic Surgeons Ltd, Norfolk, VA, ²Washington University in St Louis, MO, ³Baylor Scott & White Health, Plano, TX, ⁴Spectrum Health, Grand Rapids, MI, ⁵CorVasc MDs P.C., Indianapolis, IN, ⁶Sacramento Cardiovascular Surgeons, CA, ⁷McLaren Greater Lansing, Okemos, MI, ⁸Northwestern University/Northwestern Memorial Hospital, Chicago, IL, ⁹Old Dominion University, Norfolk, VA


Purpose: The Cox-Maze IV procedure (CM-IV) has replaced the Cox-Maze III (CM-III) as the gold standard for surgical treatment of atrial fibrillation (AF). The present FDA-regulated trial, ABLATE, seeks to demonstrate the safety and efficacy of a novel dual bipolar radiofrequency ablation device designed to create more uniform and durable lesions.

Methods: Fifty-five patients (70.5 years ± 9.3 years) underwent the CM-IV procedure to terminate AF during a concomitant open cardiac surgical procedure. Lesions were created using a dual bipolar ablation device consisting of a clamp with two pairs of ablation electrodes designed to alternate current between pairs multiple times per second. All patients were seen for follow-up visits after 30 days, 3 months, and 6 months, with a 24-hour Holter monitor at 6 months. Evaluation was also performed by 48-hour Holter monitor at a mean follow-up of 22 months for FDA panel review.

Results: The primary efficacy endpoint—absence of AF off antiarrhythmic drugs (AAD) after 6 months (HRS definition)—resulted in 76% (38/50) efficacy (95% CI: 62.6%-85.7%, see Figure 1). The primary safety endpoint—the rate of major adverse events in the first 30 days—was 9.1% (5/55, 95% CI: 3.9%-19.6%), including 3.6% mortality (2/55). Secondary efficacy endpoints (AF free independent of antiarrhythmic drug use, effectiveness of pulmonary vein isolation, overall AF burden after 6 and 12 months) and safety endpoints (composite 6-month major adverse event rate, overall adverse event rate at 6 months) likewise demonstrated that the dual bipolar device performs comparably to the gold standard CM-III. Absence of AF at 12 or more months (mean follow-up, 22 months) was 75.0% (36/48) and 62.5% (30/48) off AAD. The patient population was challenging: 93% of patients had a documented nonparoxysmal form of AF, and all patients had complex concomitant procedures (coronary artery bypass grafting surgery, valve surgery, or both).

Conclusions: The tested bipolar ablation system achieves an efficacy and safety similar to that of the most successful CM-IV studies to date, even though the patient population is unusually challenging. This result and the low rate of adverse events support greater adoption of the concomitant CM-IV procedure for nonparoxysmal AF patients.
Figure 1. Primary endpoint results. Bars show fractions for which ablation was efficacious (a) and safe (b). Error bars indicate the 95% confidence interval as computed with the Wilson score method.
Clinical Feasibility Trial for the Branched Endovascular Treatment of the Distal Aortic Arch

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REGULATORY DISCLOSURE  This presentation will address the W. L. Gore Thoracic Single Side Branch Endograft, which has an FDA status of investigational.

Purpose: Endovascular treatment for aortic arch aneurysms often requires adjunctive use of hybrid debranching procedures to maintain branch vessel perfusion. We describe early results with a novel branched arch endograft for total endovascular repair of distal arch aneurysms.

Methods: This feasibility multicenter clinical trial has enrolled 10 patients (mean age 75.2 years ± 10.0 years, 40% male) undergoing branched thoracic endovascular aortic repair (B-TEVAR) in Ishimaru zone 2. This endograft was designed with a single side branch to facilitate aortic coverage proximal to the left subclavian artery, while maintaining patency of this branch vessel. Pathology treated included fusiform (n=6) or saccular (n=4) aneurysm, with a mean aortic diameter of 5.6 cm ± 1.8 cm. Mean preoperative ankle-left brachial index (ABI) was 1.0 ± 0.1.

Results: Mean total treatment length was 20.2 cm ± 10.0 cm, with three patients treated with a single 10 cm graft for isolated arch pathology. Technical success with device delivery and branch vessel patency (primary study endpoint) was achieved in 100% of patients, without 30-day mortality, stroke, or spinal cord ischemia. Mean duration of hospitalization was 5.7 days ± 3.7 days. Endoleaks were seen in four patients (type I n=2, type II n=2, and type III n=1). Both type I and type III endoleaks resolved at 1 month. One type II endoleak resolved at 6 months; the other type II endoleak persists at 6 months without concomitant sac enlargement. Survival at 6 months is 100% for five patients. All side branches remain patent at last follow-up. Mean ABI for nine patients at 1 month was 1.1 ± 0.1.

Conclusions: Total endovascular repair of distal arch aortic aneurysms can be safely achieved with a novel branched arch endograft. Future studies will evaluate the feasibility of this approach for aneurysms encompassing the brachiocephalic trunk and left carotid artery.
The Use of MFM Technology in the Treatment of Thoracoabdominal Aortic Aneurysm and Aortic Dissection Pathology: A Single Center Experience

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REGULATORY DISCLOSURE This presentation will address the Cardiatis Multilayer Flow Modulator, which has an FDA status of investigational.

Purpose: Complex thoracoabdominal aneurysms and type B dissections involving spinal and visceral branches of the aorta are pathological entities with high-risk prognosis and actual treatment options. Multiflow modulator (MFM) technology may be a well-tolerated, safe, and effective solution.

Methods: Between December 2013 and September 2014, we treated 16 consecutive patients with abdominal or thoracoabdominal aortic aneurysms involving spinal and visceral aortic branches, as well as one case of residual type B aortic dissection (after a type A dissection treated surgically 3 months before). In all cases, the MFM was implanted on the abdominal aorta, +/- thoracic aorta, and +/- common iliac arteries when necessary. All patients had a femoral surgical approach.

Results: The mean age of patients was 66.8 years (between 28 and 78 years of age). Mean procedural time was 119.9 min, with a mean contrast loading of 91 ml. The mean air karma was 1,965.53 mGy and a mean fluoroscopy time of 21.7 min. The early results were excellent, with significant or total exclusion of the aneurysm from circulation, and the emergent branches from the aorta remaining widely patent. The mean duration of hospitalization was 5.8 days. During follow-up, reintervention was necessary in one case due to a type IB endoleak. There were no cases of early/late infection, impairment of renal function, or spinal/mesenteric ischemia.

Conclusions: The MFM technology may be the solution in the treatment of complex aortic aneurysmal pathology and type B dissection—not only in elderly patients with heavy comorbidities, but also for the younger ones, as the technology at this stage has shown low mortality, low morbidity, and low costs compared to other known techniques.
Do Current Lung Cancer Screening Guidelines Apply in Populations With High Granulomatous Disease Prevalence? Results From the First Brazilian Lung Cancer Screening Trial (BREL T1)

R. Santos¹, J. Franceschini¹, R. Chate¹, M. Ghefter¹, A. L. Trajano⁴, J. Pereira¹, J. E. Succi², H. Fernando³, R. Saad Junior⁴

¹Hospital Israelita Albert Einstein, São Paulo, Brazil, ²Federal University of São Paulo, Brazil, ³Boston Medical Center, MA, ⁴Faculdade de Ciências Médicas da Santa Casa de São Paulo, Brazil

COMMERCIAL RELATIONSHIPS  M. Ghefter: Consultant/Advisory Board, Johnson & Johnson; H. Fernando: Consultant/Advisory Board, CSA Medical, Galil

Purpose: Low-dose computed tomography screening (LDCT) for lung cancer has been demonstrated to be effective in the National Lung Screening Trial (NLST). It is unclear whether these results apply in countries with a high incidence of granulomatous disease, such as Brazil. We present results from the prevalence round of the BREL T1.

Methods: The BREL T1 was opened in January 2013. The same inclusion criteria used in NLST were applied. At the trial onset, a nodule of >4 mm was regarded as positive. Based on recent recommendations, nodules >6 mm are now considered positive. The primary outcome measure was the prevalence of lung cancer. Secondary outcomes included the number of lesions considered positive by screening criteria and the morbidity related to surgical intervention. Biopsy techniques included bronchoscopy, transthoracic needle aspiration biopsy, endobronchial ultrasound (EBUS), video-assisted thoracic surgery (VATS), or robotic video-assisted thoracic surgery (RVATS).

Results: A total of 790 patients were registered over an 18-month period. Using the 4 mm cut-off, 310 patients (39%) had positive baseline scans; therefore, a new 3- or 6-month follow-up LDCT was indicated to 278 subjects (89.7%) with positive studies. However, using the 6 mm cutoff, positive nodules were identified in 150 patients (18.9%). A total of 30 biopsy procedures were undertaken in 22 participants (3.09%) and included: CT-guided biopsy (n=10), bronchoscopy (n=7), EBUS (n=2), VATS (n=10), and RVATS (n=1). There was no mortality in VATS/RVATS, and minor morbidity occurred in two patients. Non-small cell lung cancer was diagnosed in eight patients (prevalence; 1.03%). In all cancer patients (seven cases on stages IA or IB), the only treatment was complete resection; one patient with stage IIIA disease had neoadjuvant chemotherapy performed prior to open resection (stage IB).

Conclusions: A larger number of nodules were identified in the BREL T1 compared to that reported by NLST. However, the NLST criteria to guide further intervention were still applicable, with biopsy indicated in only 3.09% and lung cancer identified in 1.09%. Current screening criteria are applicable to populations with granulomatous disease and support the role of lung cancer screening in Brazil.
Commercial Relationships of the Late-Breaking Abstract Reviewers

The Society would like to thank the following STS leaders for reviewing the late-breaking abstracts submitted for presentation consideration at the STS 51st Annual Meeting. Unless otherwise noted, the abstract reviewers have no commercial relationships to disclose:

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