Status Update and Clinical Impact of Transcatheter Aortic Valve Implantation (TAVI)

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Presenter Disclosure Information for TCTAP 2010; April 27-30, 2010

Martin B. Leon, M.D.

NON-PAID Consultant:
Edwards Lifesciences, Medtronic
Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis

First Human Case Description
Alain Cribier, MD; Helene Eltchaninoff, MD; Assaf Bash, PhD; Nicolas Borenstein, MD; Christophe Tron, MD; Fabrice Bauer, MD; Genevieve Derumeaux, MD; Frederic Anselme, MD; Francois Laborde, MD; Martin B. Leon, MD

Conclusions—Nonsurgical implantation of a prosthetic heart valve can be successfully achieved with immediate and midterm hemodynamic and clinical improvement.

April 16, 2002
THV development
A long road: 20 Years from concept to real world

April, 2010 – >15,000 implanted worldwide

1985
F.I.M. Balloon Aortic Valvuloplasty

1987
Concept of "stented valve", to rule out post-BAV valvular restenosis

1994
Post-mortem studies of intra-valvular stenting, Sketches of stented valve

1999
Sketches of stented valve "Percutaneous Valve Technology" (prototypes)

2000
First animal implantation (sheep)

2002-03
Large series of animal implantation

2002
F.I.M. PHV implantation

2002-03
Feasibility Studies (antegrade)

2004
Technological improvements

2004
Edwards Lifesciences

2005-07
International TF and TA Feasibility Studies

2007
CE mark, commercialization

2007
THV development

A long road:
20 Years from concept to real world

New York Presbyterian
Columbia University Medical Center
A Review for Innovation

Columbia University Medical Center
**TAVI in 2010**

*Exciting, “Breakthrough” Technology…Why?*

- **It’s FUN!!!**
  - requires advanced skills, discipline, persistence, and creativity
- **It’s a multi-disciplinary playground**
  - finally a “unifying” procedure which embraces surgical involvement
- **It’s incredibly fulfilling**
  - patient benefits are dramatic
- **It’s an opportunity to transform a therapy for a common disease and redefine patient care!**
Retrograde Trans-femoral Edwards Aortic Valve Deployment

Rapid pacing: 220/min
1. The “high risk” severe AS patients are “under-treated” and are excellent candidates for TAVI procedures

- Patient screening and case selection for TAVI is demanding and is critical to achieve optimal outcomes
At Least 30% of Patients with Severe Symptomatic AS are “Untreated”!

Severe Symptomatic Aortic Stenosis
Percent of Cardiology Patients Treated

<table>
<thead>
<tr>
<th>Study</th>
<th>AVR</th>
<th>No AVR</th>
<th>Percent of Cardiology Patients Treated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bouma 1999</td>
<td>41</td>
<td>59</td>
<td></td>
</tr>
<tr>
<td>Iung* 2004</td>
<td>32</td>
<td>68</td>
<td></td>
</tr>
<tr>
<td>Pellikka 2005</td>
<td>30</td>
<td>70</td>
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<tr>
<td>Charlson 2006</td>
<td>60</td>
<td>40</td>
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<tr>
<td>Bach</td>
<td>48</td>
<td>52</td>
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<tr>
<td>Spokane (prelim)</td>
<td>31</td>
<td>69</td>
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<tr>
<td>Vannan (Pub. Pending)</td>
<td>45</td>
<td>55</td>
<td></td>
</tr>
</tbody>
</table>

Under-treatment especially prevalent among patients managed by Primary Care physicians

2. Iung B et al. A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. European Heart Journal 2003;24:1231-1243 (*includes both Aortic Stenosis and Mitral Regurgitation patients)
SOURCE Registry

*EuroSCORE as a Predictor of 30-day Mortality*

**ROC Curves**

- **EuroSCORE = 20**
- **EuroSCORE = 25**
- **EuroSCORE = 30**
- **EuroSCORE = 35**

**C statistic:**
- **TF = 0.64**
- **TA = 0.61**

*Courtesy of Martyn Thomas*
Same age and predicted risk
One passes the “eyeball test” – one does not

Frailty is being studied systematically as part of the PARTNER U.S. IDE study

Photos courtesy of Michael J. Mack, MD
Medical City Dallas
Lessons Learned…

2. Multiple technology platforms have achieved excellent prosthetic valve hemodynamic results

- Both acute and mid-term valve performance has surpassed expectations
- Equivalent to surgical valve implants
TAVI Technologies

Current Generation Devices

Edwards Lifesciences

Medtronic CoreValve
TAVI Technologies

Current Generation Devices

- **Edwards Aortic Bioprosthesis**
  - Balloon expandable stainless steel bioprosthesis
  - Equine ➔ Bovine pericardial valve
  - Sheathed (RetroFlex) with tip deflection
  - Antegrade, retrograde, or trans-apical approach

- **CoreValve Revalving™ System**
  - Self-expanding nitinol cage bioprosthesis
  - Porcine pericardial valve
  - Sheathed system (low profile = 18 Fr)
  - Retrograde (femoral + subclavian) approach
The Current Generation

**Edwards – SAPIEN THV**

- Bovine Tissue
- ThermaFix Treatment
- Pericardial Mapping
- Leaflet Deflection
- Proprietary Processing

**Edwards-SAPIEN THV**

- New Skirt Height

**Untreated Equine Tissue**

**Cribier-Edwards THV**

- Current Skirt Height
Edwards *Flex Cath*
Delivery System Evolution

**Retroflex Delivery Catheter**

*Retroflex 3*  
*Retroflex 2*
Edwards Sapien XT THV

Cobalt Frame & New Leaflet Geometry

Leaflet Matching & ThermaFix

Partially Closed Design

Sapien XT

Tissue Attachment

Finite Element Analysis
Sapien XT + NovaFlex Delivery System

18 Fr profile
Transcatheter AVI

Transapical Access Route

Transfemoral

Transapical
CoreValve Self-Expanding Bioprosthesi

• **HIGHER PART:** low radial force area axes the system and increases quality of anchoring

• **MIDDLE PART:** functional valve area with three leaflets and constrained to avoid coronaries (convexo-concave) – avoids need for rotational positioning

• **LOWER PART:** high radial force of the frame pushes aside the native calcified leaflets for secure anchoring and avoids recoil and paravalvular leaks

A porcine pericardial tissue valve fixed to the frame with PTFE sutures
CoreValve ReValving System

Delivery Catheter Evolution

GEN1
8mm

GEN2
7mm

GEN3
6mm
(18 Fr)

12 Fr shaft
CoreValve ReValving™ System

18 Fr Delivery System

- Over-the-wire 0.035 compatible
- 12F Shaft
- 18F Capsule
- Loading/Release Handle

18 Fr Delivery System
CoreValve 2005

- 24 F 1st Gen CoreValve
- Surgical access and closure
- Cardiopulmonary bypass
- General anesthesia

CoreValve 2010

- 18 F 3rd Gen CoreValve
- Percutaneous access and closure
- No hemodynamic support
- Conscious sedation

PCI – like Procedure!
POOLED* Monitored Edwards TAVI

Mean Gradients and EOA (Echo)

Error bars at ±1
Standard Deviation

* REVIVE, REVIVAL, TRAVERCE
and PARTNER EU
TAVI in 2010

Lessons Learned…

3. **Multiple technology platforms have also achieved acceptable early and mid-term clinical outcomes**

- Clinical outcomes are improving, perhaps due to better patient selection, device and procedure enhancements, and “learning curve” issues
- Clinical benefit is remarkable, sustained, and very fulfilling!
- Clinical trial processes require standardization and increased rigor
TAVI in 2010

Clinical Data Conundrum…

• Early clinical trials chaotic, reflecting frequent changes in technology, procedural methods, and data collection processes (small sample sizes and difficult to pool or compare datasets)

• Study endpoints not clarified or standardized (e.g. vascular complications, para-valvular AR)

• Inconsistent use of data coordinating centers, core labs and CECs

• Poor long-term follow-up of essential valve-related endpoints (e.g. FU echoes)

• All problems exaggerated due to complexity and acuity of patient population!
What is “VARC”?  

“VARC” is the **Valve Academic Research Consortium**, an attempt to harness positive ARC methodologies, but customize the process to the special needs of valvular heart disease therapies.

**GOAL:** arrive at consensus on (1) essential endpoints and their definitions and (2) clinical trial methodology.

- **AROs** = Cardialysis, CRF, HCRI and DCRI and the Societies represented = AATS, ACC, AHA, EACTS, ESC, SCAI, and STS
- First meeting in SF at TCT on September 19th 2009; second meeting in Amsterdam on December 5-6, 2009; manuscript in preparation
Edwards TAVI
Clinical Data Sources

Edwards
- Transseptal Experience (RECAST, I-REVIVE; 36 pts)
- REVIVE (OUS, TF/TA 130 pts)
- PARTNER EU (OUS, TF/TA 130 pts)
- PARTNER FDA (US/OUS, TF/TA ~1400 pts)

Other Studies
- VANCOUVER single center (TF=164 pts, TA=86 pts)
- CANADA multi-center (6) (TF=167 pts, TA=172 pts)
- PARTNER FDA (US/OUS, TF/TA ~1400 pts)

OVERALL TOTAL 3726 PTS

FIRST-in-MAN

POST CE-APPROVAL

TOTAL = 664 PTS

PIVOTAL RCT

TOTAL = 3062 PTS
POOLED* Monitored Edwards TAVI

30-Day Mortality (vs. SOURCE)

Survival vs. Days post Procedure

**SOURCE:**
- Log-Rank p-value = 0.0226
- Hazard Ratio = 1.666
- CI = 1.068 - 2.598

**POOLED:**
- Log-Rank p-value = 0.0589
- Hazard Ratio = 1.608
- CI = 0.974 - 2.652

- **SOURCE TF (n=463):** 6.3%
- **SOURCE TA (n=575):** 10.3%
- **POOLED TF (n=222):** 10.4%
- **POOLED TA (n=281):** 16.4%

* REVIVE, REVIVAL, TRAVERCE and PARTNER EU
Vancouver TAVI Experience

Survival at 1 Year

- Transarterial
- Transapical

Valve-related
Log-rank p=0.79

All Cause
Log-rank p=0.08

TAVI in Evolution

Trans-apical

Clinical Trials

Improved short-term outcomes!
Clinical Trials

Improved short-term outcomes!
TAVI in 2010

Trans-apical

Clinical Trials

Improved one-year outcomes!
TAVI in 2010

Trans-apical

Clinical Trials

Improved one-year outcomes!
POOLED* Monitored Edwards TAVI

NYHA Class

* REVIVE, REVIVAL, TRAVERCE
and PARTNER EU
**Vancouver TAVI Learning Experience**

<table>
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<tr>
<th></th>
<th>First Half</th>
<th>Second Half</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality @ 30 days – Trans-arterial</td>
<td>10.9%</td>
<td>4.9%</td>
<td>7.9%</td>
</tr>
</tbody>
</table>

*Courtesy of John Webb*
Vancouver TAVI Learning Experience

<table>
<thead>
<tr>
<th></th>
<th>First Half</th>
<th>Second Half</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>20.9%</td>
<td>9.3%</td>
<td>15.1%</td>
</tr>
</tbody>
</table>

Mortality @ 30 days – Trans-apical

Courtesy of John Webb
4. Many TAVI complications have emerged and require further analysis and clarification

- Paravalvular AR
- Conduction disturbances
- Vascular complications
- Stroke
- Coronary obstruction
Edwards TAVI Complications

Multiple Data Sources (TA and TF)

<table>
<thead>
<tr>
<th></th>
<th>POOLED* (503 pts)</th>
<th>SOURCE (1038 pts)</th>
<th>VANCOUVER (250 pts)</th>
<th>PARIS (75 pts)</th>
<th>CA-Multictr (339 pts)</th>
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<tbody>
<tr>
<td>Vascular (maj)** (%)</td>
<td>18.5</td>
<td>10.6</td>
<td>10.3</td>
<td>11.8</td>
<td>13.1</td>
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<tr>
<td>AR &gt;2+ (%)</td>
<td>10.9</td>
<td>4.7</td>
<td>5.0</td>
<td>5.3</td>
<td>7.7</td>
</tr>
<tr>
<td>Stroke (%)</td>
<td>4.0</td>
<td>2.5</td>
<td>3.0</td>
<td>4.0</td>
<td>2.3</td>
</tr>
<tr>
<td>New Pacemaker (%)</td>
<td>4.4</td>
<td>7.0</td>
<td>5.5</td>
<td>5.3</td>
<td>4.9</td>
</tr>
<tr>
<td>Renal Failure (%)</td>
<td>5.2</td>
<td>8.7</td>
<td>4.2</td>
<td>na</td>
<td>2.6</td>
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<tr>
<td>Coronary Obstr (%)</td>
<td>0.4</td>
<td>0.6</td>
<td>na</td>
<td>0</td>
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* REVIVE, REVIVAL, TRAVERCE, PARTNER EU
** TF Only
Para-valvular Regurgitation

Patient #5
**POOLED* Monitored Edwards TAVI**

**Echo AR Results**

<table>
<thead>
<tr>
<th>Follow Up</th>
<th>Baseline</th>
<th>30 days</th>
<th>3 months</th>
<th>6 months</th>
<th>1 year</th>
<th>18 months</th>
<th>2 years</th>
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<tr>
<td>N=405</td>
<td>0.7</td>
<td>1.4</td>
<td>0.0</td>
<td>0.0</td>
<td>0.5</td>
<td>0.0</td>
<td>2.9</td>
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<tr>
<td>N=220</td>
<td>10.4</td>
<td>9.5</td>
<td>33.6</td>
<td>35.0</td>
<td>1.6</td>
<td>5.9</td>
<td>0.0</td>
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<tr>
<td>N=219</td>
<td>37.5</td>
<td>39.5</td>
<td>41.1</td>
<td>49.8</td>
<td>50.8</td>
<td>52.9</td>
<td>21.6</td>
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<tr>
<td>N=205</td>
<td>17.8</td>
<td>14.5</td>
<td>21.5</td>
<td>18.5</td>
<td>25.1</td>
<td>21.6</td>
<td>32.4</td>
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<tr>
<td>N=191</td>
<td>14.7</td>
<td>19.6</td>
<td>22.0</td>
<td>50.8</td>
<td>50.0</td>
<td>32.4</td>
<td></td>
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<tr>
<td>N=51</td>
<td>30.0</td>
<td>14.7</td>
<td>19.6</td>
<td>22.0</td>
<td>50.0</td>
<td>32.4</td>
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<tr>
<td>N=34</td>
<td>5.9</td>
<td>0.0</td>
<td>1.6</td>
<td>4.4</td>
<td>1.6</td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

**AR Grade**

- 4+
- 3+
- 2+
- 1+
- None

*REVIVE, REVIVAL, TRAVERCE and PARTNER EU*
AV-Block III° Following COREVALVE Implantation
AV-Block III° Following COREVALVE Implantation
Iliac Perforation
TAVI in 2010

Need for embolic protection...

Silent and Apparent Cerebral Ischemia After Percutaneous Transfemoral Aortic Valve Implantation: A Diffusion-Weighted Magnetic Resonance Imaging Study
Philipp Kahler, Stephan C. Knipp, Marc Schlamann, Matthias Thielmann, Fadi Al-Rashid, Marcel Weber, Uwe Johansson, Daniel Wendt, Heinz G. Jakob, Michael Forsting, Stefan Sack, Raimund Erbel and Holger Eggebrecht
Circulation 2010;121;870-878

- 32 pts with TAVI; Diffusion-Weighted MRI at baseline, post-procedure, and @ 3 mos
  - 22 balloon-expandable and 10 self-expanding THV devices
- New foci of restricted perfusion in 27/32 pts (84%)
  - Lesions usually multiple and both hemispheres (embolic)
- No impairment of neuro-cognitive function nor clinical neurologic events assoc with MRI defects
  - 80% of MRI defects resolved at 3 mos imaging study
Left Main Coronary Occlusion

(VF and SD after implant)

High implant, low left coronary ostia,
long leaflet with bulky calcified nodules

Courtesy of John Webb
5. Long-term durability evaluations of TAVI bioprosthetic valves are still ongoing

- Meticulous follow-up necessary including echocardiograms (core lab assessments)
- Ultimate value of TAVI will require proof of “near surgical” valve durability
TAVI - Durability

4 year FU specimen

Edwards
~8,000 patients

Courtesy of Dr. William O’Neill
Longest reported clinical follow-up (Rouen)

Mrs S..., 88 yo: > 6 years with THV

No valve dysfunction
AVA: 1.68 cm², mean gradient: 12 mmHg
TAVI in 2010

Lessons Learned…

6. TAVI requires a major milieu adjustment to develop an optimal program

- Hybrid cath lab - ORs
- Intense clinical care continuum – screening, procedure, pot-procedure care, follow-up
- Surgeons and interventionalists MUST work closely together (Heart Valve Team)!!!
- Strict training requirements
Transcatheter AVR

Hybrid OR-Cath Lab

A unique collaborative experience!
Transcatheter AVI

100th TAVI at Columbia...

Mat Williams
Susheel Kodali
Edwards TAVI Training Program

- Site preparation and staff training
- Didactic and case review sessions
- Complication planning
- Live case observations
- Patient screening oversight
- Case proctoring
- Critical scrutiny of clinical outcomes
The PARTNER trial should provide valuable insights and (hopefully) will provide the evidence-based medicine justification for future expansion of TAVI!

- 2 parallel Randomized clinical trials (> 1,500 patients already enrolled)
- Rigorous clinical trial methodology
- Multi-disciplinary management (surgeon = interventionalist + echo)
PARTNER Trial Design

**Fully enrolled:** continued access to both patient cohorts approved by FDA

**Primary Endpoint**
- All-cause mortality (1 yr)
- Non-inferiority

**Total = 1,052 pts**

- **Cohort A** (N=694)
  - Symptomatic Severe Aortic Stenosis
  - Assessment High Risk AVR Candidate
  - 2 Trials Individually Powered (Cohorts A & B)
  - Assessment Transfemoral Access
  - N=491
    - Trans Femoral vs AVR Control
    - Trans Apical vs AVR Control
    - 1:1 Randomization
    - PRIMARY ENDPOINT
      - All-cause mortality (1 yr)
      - Non-inferiority

- **Cohort B** (N=358)
  - Symptomatic Severe Aortic Stenosis
  - Assessment High Risk AVR Candidate
  - 2 Trials Individually Powered (Cohorts A & B)
  - Assessment Transfemoral Access
  - N=203
    - Trans Femoral vs AVR Control
    - Trans Apical vs AVR Control
    - 1:1 Randomization
    - PRIMARY ENDPOINT
      - All-cause mortality (1 yr)
      - Superiority

**Cohort A TF** (N=491)
- Trans Femoral vs AVR Control

**Cohort A TA** (N=203)
- Trans Apical vs AVR Control

**Not in Study**

**N=491**

**N=203**

**N=694**

**N=358**

**Total = 1,052 pts**
<table>
<thead>
<tr>
<th>Variable</th>
<th>Cohort A-TF (test control)</th>
<th>Cohort A-TA (test control)</th>
<th>Cohort B-TF (test control)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>450</td>
<td>182</td>
<td>430</td>
</tr>
<tr>
<td>Age (years)</td>
<td>83.6 ± 10.4</td>
<td>82.4 ± 10.8</td>
<td>83.1 ± 8.5</td>
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<tr>
<td>Gender (male)</td>
<td>58.1</td>
<td>57.4</td>
<td>48.7</td>
</tr>
<tr>
<td>Diabetes</td>
<td>40.2</td>
<td>41.7</td>
<td>35.4</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>79.5</td>
<td>79.3</td>
<td>74.0</td>
</tr>
<tr>
<td>Hypertension</td>
<td>90.0</td>
<td>95.4</td>
<td>85.3</td>
</tr>
<tr>
<td>Smoking</td>
<td>42.6</td>
<td>56.6</td>
<td>46.9</td>
</tr>
<tr>
<td>Prior MI</td>
<td>25.3</td>
<td>31.4</td>
<td>25.2</td>
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</tbody>
</table>

*subset of all randomized patients in cohort A (TF+TA) and cohort B (incl. CA)

- Preliminary snapshot
- Outcomes data blinded
# PARTNER
## High Risk Co-Morbidities (1)*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Cohort A-TF (test control)</th>
<th>Cohort A-TA (test control)</th>
<th>Cohort B-TF (test control)</th>
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</thead>
<tbody>
<tr>
<td>Number of patients</td>
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<td>182</td>
<td>430</td>
</tr>
<tr>
<td>Periph Vasc Disease</td>
<td>32.7</td>
<td>56.2</td>
<td>26.8</td>
</tr>
<tr>
<td>Hx CHF</td>
<td>97.6</td>
<td>96.6</td>
<td>97.0</td>
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<tr>
<td>NYHA Class III/IV</td>
<td>94.0</td>
<td>91.6</td>
<td>93.2</td>
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<tr>
<td>Prior CABG</td>
<td>59.5</td>
<td>69.8</td>
<td>59.5</td>
</tr>
<tr>
<td>Prior PCI</td>
<td>45.7</td>
<td>48.4</td>
<td>37.2</td>
</tr>
<tr>
<td>Prior BAV</td>
<td>15.9</td>
<td>15.9</td>
<td>25.6</td>
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<tr>
<td>Severe COPD (O2 dep)</td>
<td>7.1</td>
<td>9.7</td>
<td>23.8</td>
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*subset of all randomized patients in cohort A (TF+TA) and cohort B (incl. CA)
## PARTNER

### High Risk Co-Morbidities (2)*

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<th>Variable</th>
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<th>Cohort A-TA (test control)</th>
<th>Cohort B-TF (test control)</th>
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<tbody>
<tr>
<td>Number of patients</td>
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<td>182</td>
<td>430</td>
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<tr>
<td>CNS Disease</td>
<td>23.0</td>
<td>32.0</td>
<td>26.9</td>
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<tr>
<td>Recent Stroke/TIA</td>
<td>2.5</td>
<td>3.6</td>
<td>2.4</td>
</tr>
<tr>
<td>Cirrhosis</td>
<td>2.0</td>
<td>0</td>
<td>2.2</td>
</tr>
<tr>
<td>Porcelain aorta</td>
<td>0.4</td>
<td>1.0</td>
<td>15.1</td>
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<tr>
<td>Chest radiation</td>
<td>0.6</td>
<td>1.0</td>
<td>7.8</td>
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<tr>
<td>Chest wall deformity</td>
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<td>0</td>
<td>6.9</td>
</tr>
<tr>
<td>Frailty</td>
<td>18.9</td>
<td>17.6</td>
<td>27.9</td>
</tr>
</tbody>
</table>

*subset of all randomized patients in cohort A (TF+TA) and cohort B (incl. CA)
PARTNER Trial Design

Fully enrolled: continued access to both patient cohorts approved by FDA

Symptomatic Severe Aortic Stenosis

Assessment
High Risk
AVR Candidate

Cohort A
Cohort B

Total = 1,052 pts

N=491
N=561

Cohort A TF
Cohort B TF
Cohort A TA
Cohort B TA

1:1 Randomization

First Presentation of PARTNER Data at TCT 2010 (hopefully)!

PRIMARY ENDPOINT
All-cause mortality (1 yr)
Non-Inferiority

Superiority

Trans Femoral
AvR Control
Trans Apical
AvR Control

Not in Study

vs

Trans Femoral
AvR Control
Trans Apical
AvR Control

N=491
N=203
N=694
N=358

Total = 1,052 pts

First Presentation of PARTNER Data at TCT 2010 (hopefully)!
8. The future is exciting – TAVI procedure device enhancements (including accessories) and expanded clinical indications!

- New valve designs, lower profile systems, cerebral embolic protection, large hole vascular closure
- Clinical indications - highest priorities are “medium” or standard risk patients, AS + CAD, and bio-prosthesis valve failure
New TAVI Technologies

- Direct Flow
- Sadra
- AorTx
- Jena Valve
- HLT
- ABPS PercValve
- EndoTech
- Ventor Embracer
- Symetis
Embrella: Embolic Protection
(intra-cardiac and valve procedures)
TAVI in 2010
Cerebral Embolic Protection

Deflectors and Filters

SMT  Embrella  Claret
Percutaneous Closure

10 Fr Prostar device
TAVI in 2010

Next Clinical Targets

- Valve-in-valve for bio-prosthetic aortic and mitral valve failure
- Lower risk AS patients
- Mixed AS and CAD patients
- Asymptomatic severe AS
- Low flow - low gradient AS – impedance mismatch
- Aortic regurgitation
Transcatheter AVI

Endless Possibilities!

Trans-apical AVR

Trans-apical MVR (valve-in-valve)

Edwards-Sapien

Courtesy of Dr. John Webb
TAVI in 2010

Lessons Learned

Final Thoughts
Final Thoughts…

- Clinical “need” for TAVI in “high risk” AS patients is greater than anticipated.
- TAVI is well beyond “proof of concept” or feasibility – already being integrated into AS clinical Rx paradigms in many parts of the world.
- Technology and procedure have evolved rapidly and with proper training can be generalized to most clinical environments.
- Clinical outcomes have stabilized in experienced hands (5-10% mortality at 30 days), with late mortality reflecting underlying co-morbidities.
TAVI in 2010

Final Thoughts...

• Undeniable early and sustained clinical benefit
• Valve performance has exceeded expectations, BUT need long-term durability data
• Multi-specialty “heart valve center” concept will be the model for optimal care
• Considerations for the future – further device evolution, improved clinical research methods (“VARC” initiative), judicious extension into lower risk patient categories, and careful cost-effectiveness assessments
In the next 5-10 years, most patients with severe AS requiring AVR will be treated using transcatheter lesser-invasive modalities!
FOR MORE INFORMATION, PLEASE VISIT
www.tctconference.com

TCT2010
TRANSCATHETER CARDIOVASCULAR THERAPEUTICS 2010
THE INTERSECTION OF RESEARCH, INNOVATION AND PATIENT CARE

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