Transcatheter Aortic Valve Implantation

Present Status and Perspectives

Angioplasty Summit TCTAP 2010

Alain Cribier, MD

University of Rouen, France
Transcatheter Aortic Valve Implantation has entered the real world and is here to stay.

April 2010 ~ 15,000 THV implanted worldwide

Edwards-Sapien Balloon-Expandable Valve

CoreValve Self-Expandable Valve
Valve delivery

Edwards-Sapien Balloon-Expandable Valve

CoreValve Self-Expandable Valve
What is known in 2009

- Early prosthetic valve performance similar to surgical valve replacement
- Decreased mortality and complications with the combination of more experience, improved devices and procedural techniques, better patient screening and imaging modalities
- Marked improvement in LV function and symptoms at mid-term
- Still some device related complications (vascular events, complete AV block)

Current indications

- Severe degenerative / calcific AS
- Highly symptomatic patients
- High surgical risk or non operable
From PVT to Edwards balloon expandable Valves

**2000: PVT Valve 2003-2004**
- Percutaneous Heart Valve
  - Bovine pericardium
  - Stainless steel frame
  - 23mm

**2005-2009**
- Cribier Edwards
  - Equine pericardium
  - Stainless steel frame
  - 23mm

- Edwards Sapien
  - Treated bovine pericardium
  - Stainless steel frame
  - 23 and 26mm

**2009**
- Edwards Sapien XT
  - Next to come
  - 20mm / 29mm

**TF sheath sizes**
- 24F
- 22F
- 22F, 24F
- 18F, 19F

**Next generation**
Self expandable Medtronic CoreValve

Generation 1
25F
2004-2005

Generation 2
21F
From 2006

Generation 3
18F

Generation 4
18F
2010

Porcine pericardium valve
Nitinol stent

Improved delivery?
Improved valve designed and delivery systems

*Reduction of sheath sizes*

Edwards Sapien
(22F & 24F)

Edwards Sapien XT
(18F & 19F)

New: NovaFlex

Medtronic CoreValve

- 2004: 25F
- 2005: 21F
- 2006: 18F
### 30-day mortality and complications

<table>
<thead>
<tr>
<th>Edwards</th>
<th>PARTNER N=130</th>
<th>SOURCE N=1038</th>
<th>Webb N=168</th>
<th>FRANCE N=166</th>
<th>CoreValve</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mortality</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TF</td>
<td>8.1% 18.8%</td>
<td>6.3% 10.3%</td>
<td>8.0% 18.2%</td>
<td>8.4% 16.9%</td>
<td>10.3%</td>
</tr>
<tr>
<td>TA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Stroke</strong></td>
<td>3.0%</td>
<td>2.5%</td>
<td>4.2%</td>
<td>3.6%</td>
<td>2.2%</td>
</tr>
<tr>
<td><strong>Pacemaker</strong></td>
<td>3.0%</td>
<td>7.0%</td>
<td>5.4%</td>
<td>5.4%</td>
<td>25%</td>
</tr>
<tr>
<td><strong>Major Vascular</strong></td>
<td>10.0%</td>
<td>7.0%</td>
<td>6.6%</td>
<td>6.0%</td>
<td>7%</td>
</tr>
</tbody>
</table>
Learning curve is evident

J. WEBB et al, Circulation 2009; 119: 3009-16
No change in EOA and gradient over time

Mean Gradient and EOA Progression
Pooled monitored studies and approaches

Error bars at ± 1 Standard Deviation

EOA

Mean Gradient

349
211
202
181
174
43
27
Baseline
30 days
3 months
6 months
1 year
18 months
2 years

Edwards pooled monitored studies
All Cause Mortality Transfemoral and Early Studies

No change in E.O.A. and transvalvular gradient
PERSPECTIVES

Where do we go?

- Improved THV and delivery systems
- Upcoming controlled trials in specific subsets of pts
- Assessment of Valve + Platform durability
- THV and procedural cost / reimbursement

Expanded clinical indications?
# Valve + Platform durability is a crucial issue

Little is known on valve durability and follow-up beyond 2 years

- No case of valvular dysfunction reported so far *(unchanged E.O.A. and gradient)*

Survival ~ 60% at 2 years *(whatever the valve used)*
Longest reported clinical follow-up (Rouen)

Mrs S..., 90 y-old: >6.5 years with THV

No valve dysfunction
AVA: 1.68 cm², mean gradient: 12 mmHg
TAVI: need for additional registries and controlled trials

- Registries should report 100% in data base (SOURCE, FRANCE)
  - Controlled trials vs surgery in specific subsets of patients

  Very old patients (> 80 years) at lower risk??
  Any low risk patients ???
PERSPECTIVES ON ACCESS

Angiography + CT Scan

Diameter
Tortuositites
Calcification

Transfemoral Retrograde Approach

THV 26mm: 19F: FA > 7 mm
THV 26mm / 29mm: 18F: FA > 6 mm

2011
> 70%

Local anesthesia
Preclose technique

STENT LIKE PROCEDURES

Edwards-SAPIEN

Edwards Sapien 23mm
22F: FA > 7 mm

Edwards Sapien XT (Jan 2010)
THV 23mm: 18F: FA > 6 mm

THV 26mm: 19F: FA > 7 mm

Subclavian

Trans-apical

Medtronic
Technology advancements
Future directions

- Recoverable / repositionable
- Lower profile systems
- No perivalvular leaks
- More accurate positioning
- Percutaneous access and closure (stent like procedure)
TAVI

Interventional issues

- Importance of physician and staff training validating training and proctoring programs
- Dedicated cath-labs and / or hybrid OR with optimal imaging capabilities
- Interventional vs surgical operators no competition, no fight, optimal partnership
- Team work for screening and procedures
Conclusions
Perspectives of TAVI: my predictions

• TAVI has generated an enthusiastic response of interventionists and surgeons. In 2010, with technological advancements and optimal training, the number of centers and procedures should continue to expand in high surgical risk patients.

• In 2011/2012, depending on the results of PARTNER-US and in the event of FDA approval, TAVI might explode in USA and worldwide in this subset of high risk patients. A stent like procedure might be used in about 70% of cases.
Conclusions
Perspectives of TAVI: my predictions

• Within 5 years, expansion of indications to less severely ill patients can be expected. More indication concerning *valve+platform durability* (4 to 5 years) from previous trials and registries should be obtained before starting randomized trials in younger and otherwise healthy patients with the current devices.
Conclusions
Perspectives of TAVI: my predictions

• Within 10 years, with further improvement of the devices and procedures, and depending on the long term results of upcoming controlled trials in a broad population, TAVI may become the treatment of choice in a majority of patients with degenerative AS.