Cardiology Update Davos

TAVI: Transapical Procedures

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University Hospital Zürich
TA-AVI: antegrade, simple, safe

The front door approach!
Transapical TAVI

• Technical advantages of TA approach
• Is transfemoral better than transapical?
• Results of latest generation TA valves
• New devices for access closure and percutaneous transapical access
Transapical TAVI

- Technical advantages of TA approach
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Technical Advantages of TA approach

- Only antegrade access
- Short distance to AV, excellent control
- Facilitates coaxial orientation of implant
- Limited aortic manipulation
- Limited radiation exposure
- No limitations for diameter
  - allows for larger, (cuffed) devices
Direct antegrade vs remote retrograde access
TA-AVI: Coaxial orientation of implant

- Antegrade, coaxial orientation
- Easy wire adjustments
Transapical TAVI

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Transapical TAVI

- Technical advantages of TA approach
- Is transfemoral better than transapical?
  - Mortality
  - Complications
Canadian experience TF - TA
No difference in outcomes
Transapical AVI only in case of poor vascular access – transfemoral first strategy
<table>
<thead>
<tr>
<th></th>
<th>TF = 162</th>
<th>TA = 177</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral vascular disease</td>
<td>19%</td>
<td>50%</td>
</tr>
<tr>
<td>STS Score</td>
<td>9%</td>
<td>10.5%</td>
</tr>
<tr>
<td>30-day mortality</td>
<td>9.5%</td>
<td>11.3%</td>
</tr>
<tr>
<td>1 year survival</td>
<td>75%</td>
<td>78%</td>
</tr>
<tr>
<td>2 year survival</td>
<td>65%</td>
<td>64%</td>
</tr>
</tbody>
</table>
No difference in survival for TF vs TA in propensity matched groups.
TA: PARTNER (n=104) versus continued access (n=822)

- AVR
- PMA-TA
- NRCA-TA

No. at Risk

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>3</th>
<th>6</th>
<th>9</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVR</td>
<td>92</td>
<td>76</td>
<td>71</td>
<td>70</td>
<td>67</td>
</tr>
<tr>
<td>PMA-TA</td>
<td>104</td>
<td>87</td>
<td>82</td>
<td>76</td>
<td>73</td>
</tr>
<tr>
<td>NRCA-TA</td>
<td>822</td>
<td>571</td>
<td>370</td>
<td>297</td>
<td>126</td>
</tr>
</tbody>
</table>

PARTNER TF (n=492): 22.2 @1yr

Stroke 2% @ 30d

3.9% @ 1yr
Outcomes After Transcatheter Aortic Valve Implantation: Transfemoral Versus Transapical Approach

Log-rank P=0.63

Patients at risk
TFA 45 36 33 26 23
TAA 59 50 36 28 20

*P=NS

Ewe ATS 2011
“Early, midterm, clinical, and echocardiographic outcomes were comparable in both approaches. However, TAA has the additional benefit of reducing radiation exposure (5 vs 12 min) and contrast use (173 vs 80ml) intraoperatively without prolonging the length of hospital stay.”
Transapical TAVI

• Technical advantages of TA approach

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  - Mortality
  - Complications
USZ TAVI Experience: VARC Prosthesis Associated Complications

Grouped by procedure

Grouped by prosthesis

Transapical

Transarterial

Log-rank p = 0.46

Edwards SAPIEN

Medtronic CoreValve

Log-rank p = 0.004
USZ TAVI Experience: VARC Combined Efficacy Endpoint

Grouped by procedure

Grouped by prosthesis

Patients with effective TAVI therapy

No. at Risk
TAP 27   TF 76

Days
18   46
14   30

p=0.8
Femoral
Apical

No. at Risk
CV 61   ES 42

Days
40   24
29   15

p=0.74
Medtronic CoreValve
Edwards SAPIEN
USZ TAVI Experience: 30-Day (VARC) MACCE Rate

- Mortality: 10.5%
- Bleeding: 8.5%
- Vascular Compl.: 11.5%
- AKI: 6%
- AMI: 1.5%
- Stroke: 0.8%
Vascular complications

Metaanalysis 3519 patients from 16 studies

Genereux P JACC 2012
GARY-Registry Results – Procedure

Vascular complications

- n=6517
- n=3458
- n=2689
- n=1177

- without CABG: 1.0%
- with CABG: 1.6%
- transvascular: 11.9%
- transapical: 2.5%

Data presented by Figulla at TCT 2012
Vascular complications with TF approach: bleeding
Vascular complications with TF approach: occlusion
Vascular complications with TF approach: dissection
Vascular complications with TF approach
Transfemoral (Sapien) : Major Vascular/Access Complications 30 d Source Registry (n=463)

<table>
<thead>
<tr>
<th>Vascular Complications</th>
<th># events/pts</th>
<th>% pts with event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access Related Complications</td>
<td>91/83</td>
<td>17.9%</td>
</tr>
<tr>
<td>Aortic Dissections (AD below)</td>
<td>9/9</td>
<td>1.9%</td>
</tr>
<tr>
<td>Non-Access Related</td>
<td>6/5</td>
<td>1.1%</td>
</tr>
<tr>
<td>All Vascular Complications</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Major (includes aortic dissection)</strong></td>
<td>55/49</td>
<td>10.6%</td>
</tr>
<tr>
<td>Minor</td>
<td>51/48</td>
<td>10.4%</td>
</tr>
</tbody>
</table>

Death rate in patients without event vs Death rate in patients with event:

- Transfemoral Major Vascular / Access Complication: 5.6% vs 12.2%
TA access related complication rate

Source: 0.6%,
Prevail: 0.7%
# TAVI - Stroke

<table>
<thead>
<tr>
<th>Registry</th>
<th>n</th>
<th>ES</th>
<th>30d mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>German¹</td>
<td>697</td>
<td>20.5</td>
<td>12.4%</td>
</tr>
<tr>
<td>French²</td>
<td>244</td>
<td>25.6</td>
<td>12.7%</td>
</tr>
<tr>
<td>French 2³</td>
<td>759</td>
<td>22-24</td>
<td>7.8-11.3%</td>
</tr>
<tr>
<td>Belgian⁴</td>
<td>328</td>
<td>28</td>
<td>11%</td>
</tr>
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</table>

- **Stroke 2.8 -7.7%¹-⁴**
- **Permanent pacer  9.4 - 39%¹-⁴**
- **Moderate paravalvular AI**
  independent predictor of late death⁵

¹ EHJ 2011
² EHJ 2011
³ unpublished data
⁴ ICTVS 2011
⁵ Heart 2011
TA: consistently lower stroke risk

Risk of stroke after transcatheter aortic valve implantation (TAVI): a meta-analysis of 10,037 published patients

<table>
<thead>
<tr>
<th>n</th>
<th>TF/TA</th>
<th>MCV/ES</th>
<th>Log. EuroScore</th>
<th>Stroke / TIA 30-days</th>
</tr>
</thead>
<tbody>
<tr>
<td>3236</td>
<td>TF</td>
<td>MCV</td>
<td>22 %</td>
<td>3.1 ±2.2 %</td>
</tr>
<tr>
<td>1733</td>
<td>TF</td>
<td>ES</td>
<td>26 %</td>
<td>4.2 ±2.2 %</td>
</tr>
<tr>
<td>2482</td>
<td>TA</td>
<td>ES</td>
<td>29 %</td>
<td>2.7 ±1.4 %</td>
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Risk of stroke after TAVI: a meta-analysis of 10,037 published patients.

- Fifty-three studies including a total of 10,037 patients
- Procedural stroke (<24 h) occurred in 1.5 ± 1.4%
- 30-day stroke/TIA was 3.3 ± 1.8%
- Differences in stroke rates were associated with different approaches and valve prostheses used
- Lowest stroke rates after transapical TAVI (2.7 ± 1.4%)
Results – Outcome

Cerebrovascular Events

<table>
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<tr>
<th>Procedure</th>
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<th>n=3458</th>
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<tr>
<td>without CABG</td>
<td>2.2%</td>
<td>3.6%</td>
<td>3.7%</td>
<td>3.5%</td>
</tr>
<tr>
<td>with CABG</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>transvascular</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>transapical</td>
<td></td>
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Data presented by HR Figulla @ TCT 2012
TAVI – permanent pacer

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- Stroke 2.8 -7.7%¹⁻⁴
- Permanent pacer 9.4 - 39%¹⁻⁴
- Moderate paravalvular AI independent predictor of late death⁵

¹ EHJ 2011
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³ unpublished data
⁴ ICTVS 2011
⁵ Heart 2011
GARY-Registry Results – Procedure

New Pacemaker

- without CABG: 4.6%
- with CABG: 3.9%
- transvascular: 23.7%
- transapical: 9.9%

Data presented by HR Figulla at TCT 2012
TAVI – paravalvular leakage

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<th>Registry</th>
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</tr>
</thead>
<tbody>
<tr>
<td>German(^1)</td>
<td>697</td>
<td>20.5</td>
<td>12.4%</td>
</tr>
<tr>
<td>French(^2)</td>
<td>244</td>
<td>25.6</td>
<td>12.7%</td>
</tr>
<tr>
<td>French 2(^3)</td>
<td>759</td>
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<td>Belgian(^4)</td>
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<td>11%</td>
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- Stroke 2.8 -7.7%\(^1-4\)
- Permanent pacer 9.4 - 39%\(^1-4\)
- **Moderate paravalvular AI**
  - independent predictor of late death\(^5\)

1 EHJ 2011
2 EHJ 2011
3 unpublished data
4 ICTVS 2011
5 Heart 2011
Effect of paravalvular leakage on survival
PARTNER 2y FU: TAVI group

C. Severity of Total Aortic Regurgitation: None or Trace versus Mild to Severe
Hazard ratio, 1.75 (95% CI, 1.17–2.61)
P = 0.006 by log-rank test

D. Severity of Total Aortic Regurgitation: None or Trace, Mild, or Moderate to Severe
P < 0.001 by log-rank test
1 year Actuarial mortality according to post-procedural aortic regurgitation

Survival, %

Days

AR grade = 0
AR grade = 1
AR grade ≥ 2

p=0.0001

10% mortality

25% mortality

Data presented at TCT 2012 by E Van Belle
FRANCE II Registry – rate of PVL

Grade 0

Grade 1

Grade 2

Grade 3

Transfemoral

Transapical

Gilard M NEJM 2012
Conclusion from FRENCH II Registry

- The occurrence of post-procedural perivalvular AR grade ≥2 was observed in about 15% after a successful TAVI procedure in the FRANCE2 Registry.
- Its occurrence was associated with a 2 fold increase in 1-year mortality rate and was the strongest and independent predictor of 1-year mortality.

- Among procedural parameters, the use of a Self expendable device and of a femoral delivery approach were the 2 major determinants of AR (HR>2).
Transapical TAVI

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Jena Valve - Valve Design

- Native porcine aortic valve
- Self-expanding Nitinol stent with flexible stent posts
- "Feeler" for anatomically correct positioning
- Clipping fixation to leaflets
- Sizes 23, 25, 27 mm
- Device retrieval capability

CE mark as of October 2011
Jena Valve – Three Step Delivery System

Step 1
- Unsheathing of Feelers
- Orientation of Markers
- Anatomically Correct Positioning

Step 2
- Clipping on native leaflets

Step 3
- Final Valve Release
- Correct positioning
- No Rapid Pacing needed
Medtronic Engager Transcatheter Valve

- Dedicated commissural posts
- Nitinol main frame
- Scalloped bovine Pericardial leaflets
- Nitinol support frame
- Polyester skirt

• Self-guided, reproducible, intuitive deployment into an anatomically correct supraannular position
• Relies on axial in addition to radial forces for fixation
• Leaves the coronary ostia unobstructed and accessible
Engager Control Arm Function

- **Precise Valve Positioning**: Control arms provide tactile feedback and stabilize bioprosthesis during deployment.

- **Minimal Paravalvular Leak**: Control arms capture the native leaflets and the self-expanding frame conforms to the annulus.

Control arms are released as the first stage in device deployment and are placed in contact with the native leaflets.
Symetis AcurateValve (CE 2011)

- porcine aortic valve
  - non coronary leaflets
- Self-expanding Nitinol
- Sizes 23, 25, 27 mm

STABILIZATION ARCHES
- Flexible
- Self-aligning

UPPER CROWN
- Supra-annular anchoring
- Stable positioning
- Easy placement
- Tactile feedback

LOWER CROWN / PET SKIRT
- Minimal stent protrusion into LV
- Seals within the native annulus
### 30 day outcomes

<table>
<thead>
<tr>
<th></th>
<th>Log ES</th>
<th>Survival 30d</th>
<th>Stroke 30d</th>
<th>PVL 2+ or &gt;2+</th>
<th>P mean</th>
<th>New PM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jena (73)</td>
<td>28.4</td>
<td>92.5</td>
<td>3.0</td>
<td>13.6</td>
<td>10.0</td>
<td>10.6</td>
</tr>
<tr>
<td>Engager (61)</td>
<td>18.9</td>
<td>90.1</td>
<td>1.8</td>
<td>3.3</td>
<td>11.5</td>
<td>30.2</td>
</tr>
<tr>
<td>Symetis (90)</td>
<td>20.2</td>
<td>92.2</td>
<td>3.3</td>
<td>2.9</td>
<td>11.6</td>
<td>11.1</td>
</tr>
<tr>
<td>Symetis (250)</td>
<td>22.3</td>
<td>95.2</td>
<td>0.8</td>
<td>3.8*</td>
<td>12.8*</td>
<td>4.8</td>
</tr>
<tr>
<td>GARY (1181)</td>
<td>22.4</td>
<td>92.3</td>
<td>3.5</td>
<td>-</td>
<td>-</td>
<td>9.9</td>
</tr>
</tbody>
</table>

*data from 150 pts.*
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• New devices for acces closure and percutaneous transapical access
TA: Occlusion devices

*Outlook on new transapical companion devices*

Apica

Permaseal

EnTourage
Cardioclose™ transapical closure system

- Anchored sutures
- Potential for percutaneous access and closure
FIH „closure device“ – Apica
CARDIAPEX
A NEW PORT INTO THE HEART
Crimping / sheath diameter may affect structural integrity

Less crimping => improved durability !?

1 day crimped => fragmentation


Solutions to reduce PV leak:

- Cloth may better seal off against PV leaks.
- Hydrophilic coatings
Transapical TAVI

• Safe antegrade approach
• Ease of implantation
• Low complication rate
• Outcomes comparable or better to TF
• No limits with regards to size or design of prosthesis
Transapical approach: A window of opportunity!

- Aortic valve
- Mitral valve
- Mechanical Circulatory Assist systems
- Hybrid procedures
- ...

...