Tricuspid Valve Implantation: Current Data and Future Perspectives

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No Disclosures
Catheter treatment of tricuspid valve insufficiency

• More technical challenges compared to other valve interventions:
  - Proximity of AV node and RCA
  - Leaflets and chordae are thinner than in mitral
  - Thin RV wall
  - Many patients have pacemaker leads

• Patient selection is difficult
  - difficult assessment of symptoms, variability of clinical status …
  - when is it too late and when too early?

• Imaging is difficult

• All repair techniques are in an early stage

• Tricuspid valve implantation may be an alternative
Transcatheter Tricuspid Valve Implantation

- Valve in surgical valve
- Ectopic valve implantation
  - Caval valve implants
  - CaValve
- CavalveTricuspid valve in native valve implantation
  - NaviGate
  - Trisol
  - LuX-Valve
Tricuspid Valve in Surgical Valve

J.S., 32 y/o, m
S.P. Tricuspid valve implantation at the age of 14 due to Epstein syndrome with tricuspid stenosis

Degenerated surgical valve: 31 mm-Carpentier-Edwards

Transcatheter valve: 29 mm Sapien XT
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  - Trisol
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Transcatheter CAVI

- Implantation of self-expandable valve in SVC
- Implantation of self-expandable valve in IVC at cavo-atrial junction above hepatic vein inflow

Alexander Lauten, Hans R. Figulla
Results

- FIM CAVI 08/2010 - Inclusion 08/2010 – 02/2017, 7 centers (6 in Germany, 1 in Canada)
- 100% compassionate cases

(C) Tricuspid Annular Plane Systolic Excursion

(D) Cardiac Index

(E) IVC Hemodynamics

(F) RA Hemodynamics

NYHA-Class
Baseline vs. Discharge

Lauten A Circ Cardiovasc Interv 2018;
New concept: Cavalive

A stent graft structure that regulates inflow to RA through the stent graft wall

Anchoring is done in the tubular SVC and IVC

The stent graft can bare multiple valves

The native valve is left untouched

Pre-clinical
Transcatheter Tricuspid Valve Implantation

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  - CaValve
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  - NaviGate
  - Trisol
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Valve in Native Valve: NaviGate Tricuspid Valve

- Made of a nitinol tapered stent, height 21 mm
- Annular winglets and leaflet anchors
- Valve sizes 36, 40, 44, 48, 52 mm
- 35 F sheath with OD 42 F
- Trans-jugular or right-atrial (mini-thoracotomy)
- Delivery system has two degrees of tip motion and allows a very controlled valve release
Transjugular access

- Internal jugular vein > 14mm
- > 7cm space between the sheath and the tricuspid valve
Preferred access: Transatrial
navigate tricuspid valve implantation
1st patient in frankfurt

- 80 y/o male patient
- S.P. surgical mitral valve replacement at the age of 61
- EF 45 %
- Severe tricuspid insufficiency
  - Recurrent hospital admissions due to right heart failure with severe pleural effusion, edema and ascites
- Atrial fibrillation
- Hypertension
- AAA
• Patient has also a mechanical valve in mitral position
• RV angiogram shows a very severe tricuspid regurgitation
• Right atrial access obtained via lateral mini-thoracotomy
• Stiff wire RA-RV-PA
• Coronary wire in the RCA for fluoro guidance
• Navigate valve just prior to deployment
• During deployment, ventricular tines are exposed
• After deployment

CVC Frankfurt
Navigate tricuspid valve implantation
1st patient in Frankfurt

before

after

CVC Frankfurt
## Patients (All Centers)

<table>
<thead>
<tr>
<th>Site/City</th>
<th>Country</th>
<th>TA</th>
<th>TJ</th>
<th># of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laval, Quebec</td>
<td>Canada</td>
<td>3</td>
<td>0</td>
<td>3</td>
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<tr>
<td>St. Michaels, Toronto</td>
<td>Canada</td>
<td>5</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>San Borja, Santiago</td>
<td>Chile</td>
<td>1</td>
<td>0</td>
<td>1</td>
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<tr>
<td>CVC, Frankfurt</td>
<td>Germany</td>
<td>2*</td>
<td>2*</td>
<td>4</td>
</tr>
<tr>
<td>Padua, Padua</td>
<td>Italy</td>
<td>0</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>San Raffaele, Milan</td>
<td>Italy</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>John Paul II, Krakow</td>
<td>Poland</td>
<td>2</td>
<td>1</td>
<td>3</td>
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<tr>
<td>Puerta De Hierro, Madrid</td>
<td>Spain</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>USZ, Zurich</td>
<td>Switzerland</td>
<td>4</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>CCF, Cleveland</td>
<td>USA</td>
<td>3</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>CUMC, New York</td>
<td>USA</td>
<td>5</td>
<td>0</td>
<td>5</td>
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<td>Northwestern, Chicago</td>
<td>USA</td>
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<td>0</td>
<td>1</td>
</tr>
<tr>
<td>SFH, Roslyn, NY</td>
<td>USA</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>29</td>
<td>8</td>
<td>37</td>
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## Patient baseline characteristics

<table>
<thead>
<tr>
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<th>% or Mean ± SD</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>73.5 ± 12.5 yrs</td>
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<tr>
<td>Female</td>
<td>53%</td>
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<tr>
<td>Baseline NYHA class III or IV</td>
<td>63%</td>
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<tr>
<td>Atrial fibrillation</td>
<td>84%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>59%</td>
</tr>
<tr>
<td>CAD</td>
<td>63%</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>41%</td>
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<tr>
<td>Prior valve interventions</td>
<td>66%</td>
</tr>
<tr>
<td>Valve surgery (2x mitral, 1x aortic, 1x aortic &amp; mitral)</td>
<td>44%</td>
</tr>
<tr>
<td>Transcatheter valve repair/replacement</td>
<td>22%</td>
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<tr>
<td>Renal dysfunction</td>
<td>59%</td>
</tr>
<tr>
<td>RV Dysfunction</td>
<td>84%</td>
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<tr>
<td>Prior stroke or TIA</td>
<td>9%</td>
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<tr>
<td>Systemic hypertension</td>
<td>41%</td>
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<tr>
<td>Prior intracardiac device (PPM or ICD)</td>
<td>19%</td>
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<tr>
<td>Heart transplant</td>
<td>9%</td>
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</table>

Very sick patient population!
Acute results

<table>
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<tr>
<th></th>
<th>TA</th>
<th>TJ</th>
<th>Total</th>
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<tbody>
<tr>
<td>Attempts</td>
<td>29</td>
<td>8</td>
<td>37</td>
</tr>
<tr>
<td>Successful implant (pts)</td>
<td>24</td>
<td>3</td>
<td>27</td>
</tr>
<tr>
<td>Implantation not successful*</td>
<td>1</td>
<td>4</td>
<td>5</td>
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<tr>
<td>Conversion to surgery</td>
<td>4</td>
<td>1</td>
<td>5</td>
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</tbody>
</table>

*2 Intent-to-treat patients by TJ-access became TA – access patients at a later time. Hence total number of patients is 32
Tricuspid Regurgitation

Pre

Post

NYHA Class

NaviGate Transcatheter Tricuspid Valve Implants

NaviGate Cardiac Structures, Inc.
Trisol

- Unique valve design
- Transjugular approach
- 30F delivery system
- The valve anchors on the leaflets
- Can be repositioned and retrieved
- Animal test ongoing
LuX-Valve

- Soft Valve Disc
  - Attached on the leaflets and TV annulus
  - Sizes: 50, 60, 70mm
- Two graspers for anterior leaflet
- One interventricular anchor (IVA)
- Inner diameter: 26 or 28mm
- Valve size based on effective orifice area – not size of annulus
- Fixation not dependent on radial force
  - depends on anterior cusp and interventricular septum
- Avoids paravalvular leak by the attachment between disc and leaflets
LuX-Valve

Preoperative TEE

Postoperative TEE

China Valve, Zhiyun Xu, Fanglin Lu
LuX-Valve - Early clinical results

- n=15
- Successful implantation in all patients
- 30-day mortality 6.7%
  - 1 Death due to myocardial infarction

<table>
<thead>
<tr>
<th></th>
<th>Before Operation</th>
<th>Post operation</th>
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<tbody>
<tr>
<td>LVEF</td>
<td>54.7±6.5</td>
<td>55.7±5.1</td>
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<tr>
<td>Prosthetic valve migration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regurgitation (ml)</td>
<td>47.5±10.3</td>
<td>0</td>
</tr>
<tr>
<td>Perivalvular leakage (ml)</td>
<td>1.9±1.9</td>
<td></td>
</tr>
<tr>
<td>Transtricuspid gradient (mmHg)</td>
<td>1.1±0.2</td>
<td>1.0±0.3</td>
</tr>
<tr>
<td>Tricuspid annulus diameter (mm)</td>
<td>45.5±4.3</td>
<td>40.5±4.3</td>
</tr>
<tr>
<td>RA Volume (ml)</td>
<td>194.0±108.6</td>
<td>160.8±57.3</td>
</tr>
<tr>
<td>RV volume (ml)</td>
<td>71.9±11.4</td>
<td>65.4±20.3</td>
</tr>
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Tricuspid valve implantation has taken off!