Transcatheter Implantation of Self-Expandable Vena Cava Valves for Treatment of TR (CAVI)

First-Human-Case Description

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

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<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
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<tbody>
<tr>
<td>• Major Stock Shareholder/Equity</td>
<td>• JenaValve, Occlutech</td>
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<tr>
<td>• Ownership/Founder</td>
<td>• JenaValve, Occlutech</td>
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Etiology and Treatment of Tricuspid Regurgitation:

- TR functional in up to 90% of all patients
- Prevalence US-Population: 1.6 Mio pts.
- Poor prognosis (1-year mortality)
  - mild: 9.7%
  - moderate: 21.1%
  - severe: 36.1%
- Surgical Repair:
  - Operative mortality: 12-26%
  - metaanalysis (1258 pts): 19%

* Nath J et al. JACC 2004; 43(3) 405-9
Self-expanding valves in **central venous position** to reduce venous congestion
Preclinical Studies and „First-in-Man“ IVC-Valve Implantation

To the Editor: Tricuspid regurgitation (TR) in patients with late-stage myoccardial and valvular disease leads to a decrease in cardiac output with significant symptoms of right heart failure development. Percutaneous TR leads to a decrease in cardiac output with significant symptoms of right heart failure development.

To date, no percutaneous approach to TR exists in clinical routine, but several research groups have been working on percutaneous TR repair or replacement.

Percutaneous caval stent valve implantation: investigation of a new transcatheter valve for treatment of tricuspid regurgitation

Heterotopic transcatheter tricuspid valve implantation: first-in-man application of a novel approach to tricuspid regurgitation
Bi-Caval Self-Expandable Valve Implantation - „First in Man“
Patient: Clinical Presentation & Hemodynamics

- 83-year old female with severe, long-standing functional and structural TR

- refractory symptoms of RV- failure
  - NYHA IV and orthopnea
  - peripheral edema and ascites

- congestive hepatic dysfunction
  - albumine 23g/l (31-45g/l)
  - cholinesterase 45µmol/l*s (65-180µmol/l*s)
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Interventional Concept – Transcatheter CAVI

- Implantation of self-expandable valve in SVC
- Implantation of self-expandable valve in IVC at cavo-atrial junction above hepatic vein inflow
Device: Self-Expanding Bioprosthetic Valves

- Self-expandable pericardial tissue valve on nitinol stent frame
  - IVC: 70x43mm
  - SVC: 60x38mm
- 27F flexible catheter for transvenous implantation
CAVI Procedure - Valve Deployment

- Loading and ...
- Deployment of SVC-Valve
- Loading and ...
- Deployment of IVC-Valve
Device Function: Transesophageal Echo

- immediate device function confirmed by echo
Hemodynamic Changes after CAVI

- Before:
  - SVC: 27mmHg
  - RA: 32mmHg
  - IVC: 28mmHg

- After:
  - SVC: 21mmHg
  - RA: 37mmHg
  - IVC: 16mmHg

... and improvement of invasive hemodynamics
Clinical Course After CAVI

- uneventful recovery
- patient resumed off-bed activities after 24 hours
- anticoagulation with warfarin
- discharged home after 10 days and continued on ambulantory follow-up
Hemodynamics and Clinical Condition

3 month after CAVI

- excellent device function after 3 month
  - IVC: 28/15 mmHg → 13/6 mmHg
  - SVC: 27/14 mmHg → 21/7 mmHg

- NYHA IV → NYHA II

- 6min walk test: 20m → 200m

- normalization of liver function
  - albumine 36g/l (31-45g/l)
  - cholinesterase 89 µmol/l*s (65-180µmol/l*s)
2011: Autopsy Result of First Human IVC-Valve Implantation

- correct device position
- stent fully covered with fibrous tissue, making the device "unretrievable"
- no obstruction of hepatic veins
- excellent device function, minor paravalvular leakage
Clinical Data in the Literature

- limited experience in the literature
- recent report by Laule et al. using balloon-expandable valves in SVC and IVC
- “presenting” with self-expandable stent

Laule et al., JACC 2013
Conclusions

- CAVI is a technically feasible procedure with a simple and straightforward implantation technique.
- CAVI results in greater hemodynamic and symptomatic improvement than single IVC-valve implantation alone.
- Concept aimed for severely ill, non-surgical patients with TR, however:
Limitations & Unresolved Problems

- long-term benefit in this severely ill patient population unknown
- potential deleterious effects on cardiac function and rhythm from persisting volume overload
- anatomical variations and diameter of IVC requires specific, potentially individually designed devices
Thank you!

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