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

First-Human-Case Description



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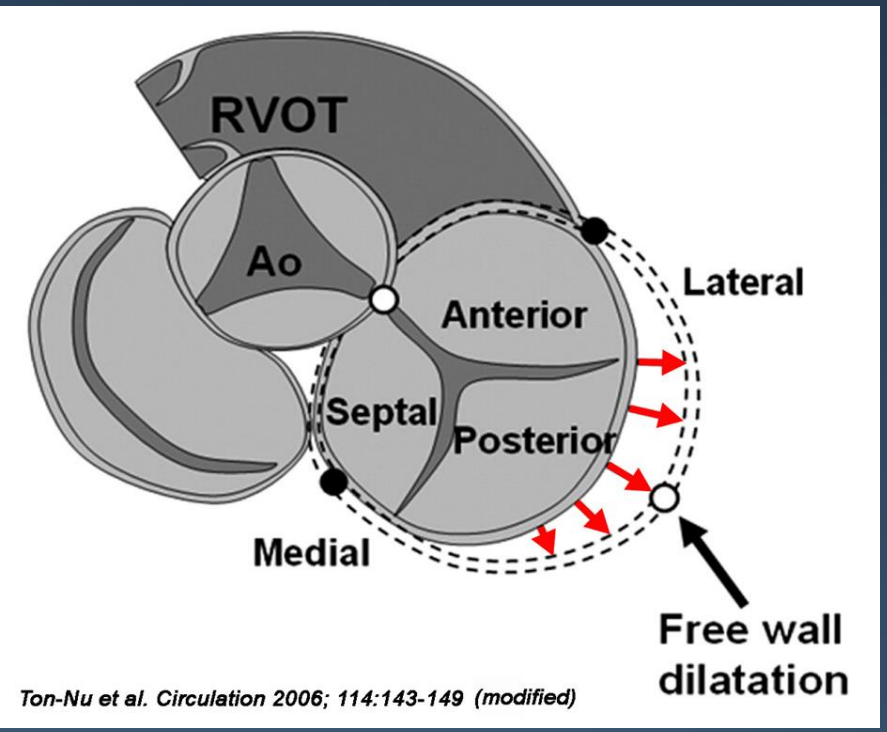
Disclosure Statement of Financial Interest

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

Affiliation/Financial Relationship	Company
• Major Stock Shareholder/Equity	• JenaValve, Occlutech
• Ownership/Founder	• JenaValve, Occlutech

Etiology and Treatment of Tricuspid Regurgitation:

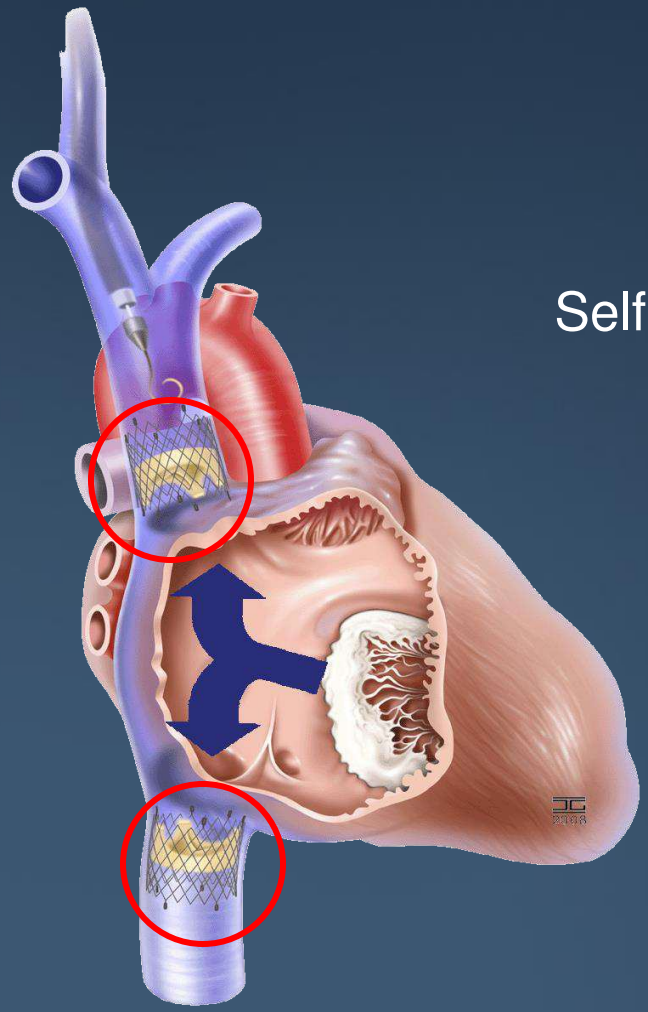


Ton-Nu et al. Circulation 2006; 114:143-149 (modified)

- TR <u>functional</u> 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%

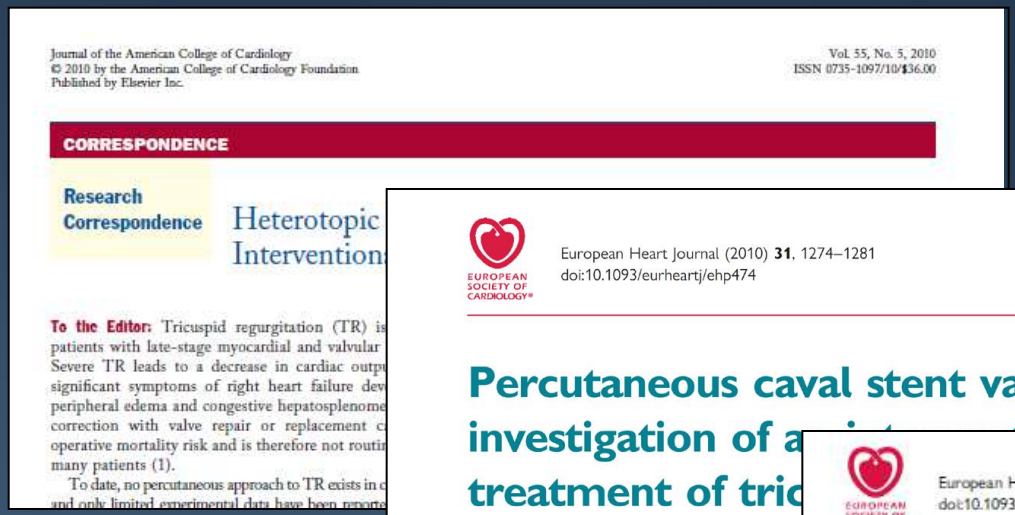
** Nath J et al. JACC 2004; 43(3) 405-9*

Bi- Caval Valve Implantation - *CAVI*



Self-expanding valves in **central venous position**
to reduce venous congestion

Preclinical Studies and „First–in–Man“ IVC–Valve Implantation



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CORRESPONDENCE

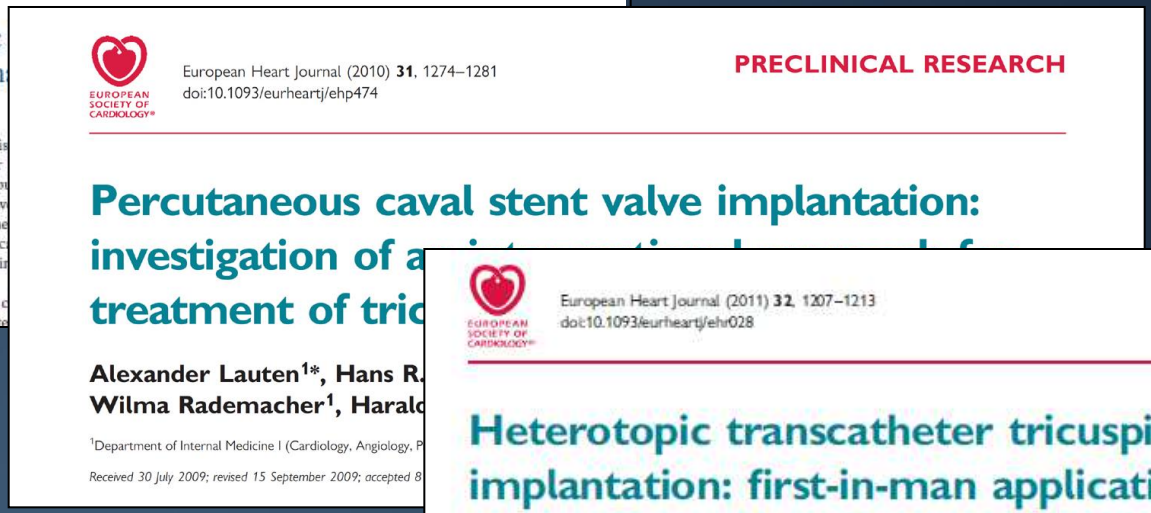
Research Correspondence

Heterotopic
Intervention

To the Editor: Tricuspid regurgitation (TR) is
patients with late-stage myocardial and valvular
Severe TR leads to a decrease in cardiac outpu
significant symptoms of right heart failure dev
peripheral edema and congestive hepatosplenome
correction with valve repair or replacement c
operative mortality risk and is therefore not routi
many patients (1).

To date, no percutaneous approach to TR exists in c
and only limited experimental data have been reporte

JACC 2010



European Heart Journal (2010) **31**, 1274–1281
doi:10.1093/eurheartj/ehp474

PRECLINICAL RESEARCH

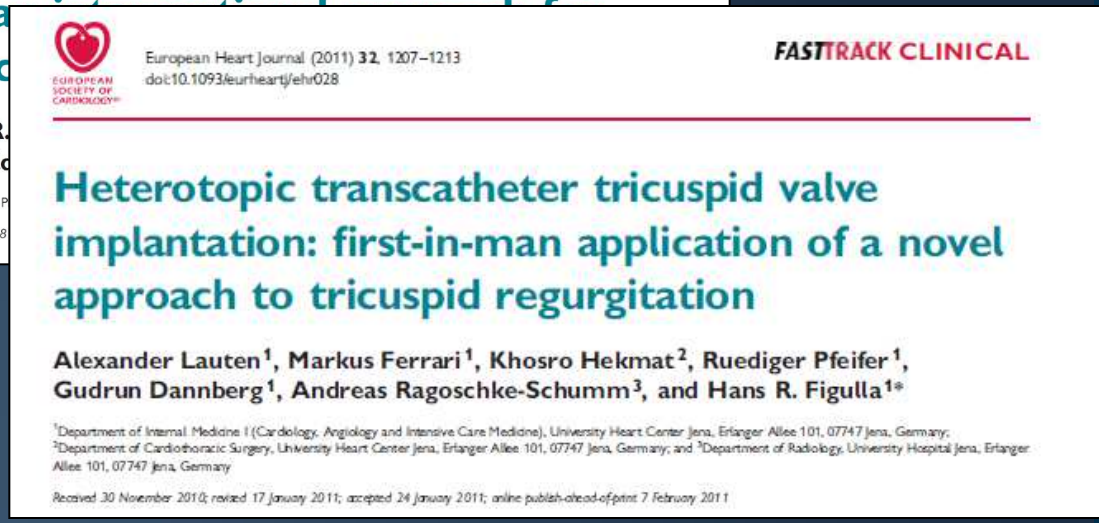
Percutaneous caval stent valve implantation: investigation of a
treatment of tric

Alexander Lauten[1]*, Hans R.
Wilma Rademacher[1], Haralc

[1]Department of Internal Medicine I (Cardiology, Angiology, P

Received 30 July 2009; revised 15 September 2009; accepted 8

EHJ 2010



European Heart Journal (2011) **32**, 1207–1213
doi:10.1093/eurheartj/ehr028

FASTTRACK CLINICAL

Heterotopic transcatheter tricuspid valve implantation: first-in-man application of a novel approach to tricuspid regurgitation

Alexander Lauten[1], Markus Ferrari[1], Khosro Hekmat[2], Ruediger Pfeifer[1], Gudrun Dannberg[1], Andreas Ragoschke-Schumm[3], and Hans R. Figulla[1]*

[1]Department of Internal Medicine I (Cardiology, Angiology and Intensive Care Medicine), University Heart Center Jena, Erlanger Allee 101, 07747 Jena, Germany; [2]Department of Cardiothoracic Surgery, University Heart Center Jena, Erlanger Allee 101, 07747 Jena, Germany; and [3]Department of Radiology, University Hospital Jena, Erlanger Allee 101, 07747 Jena, Germany

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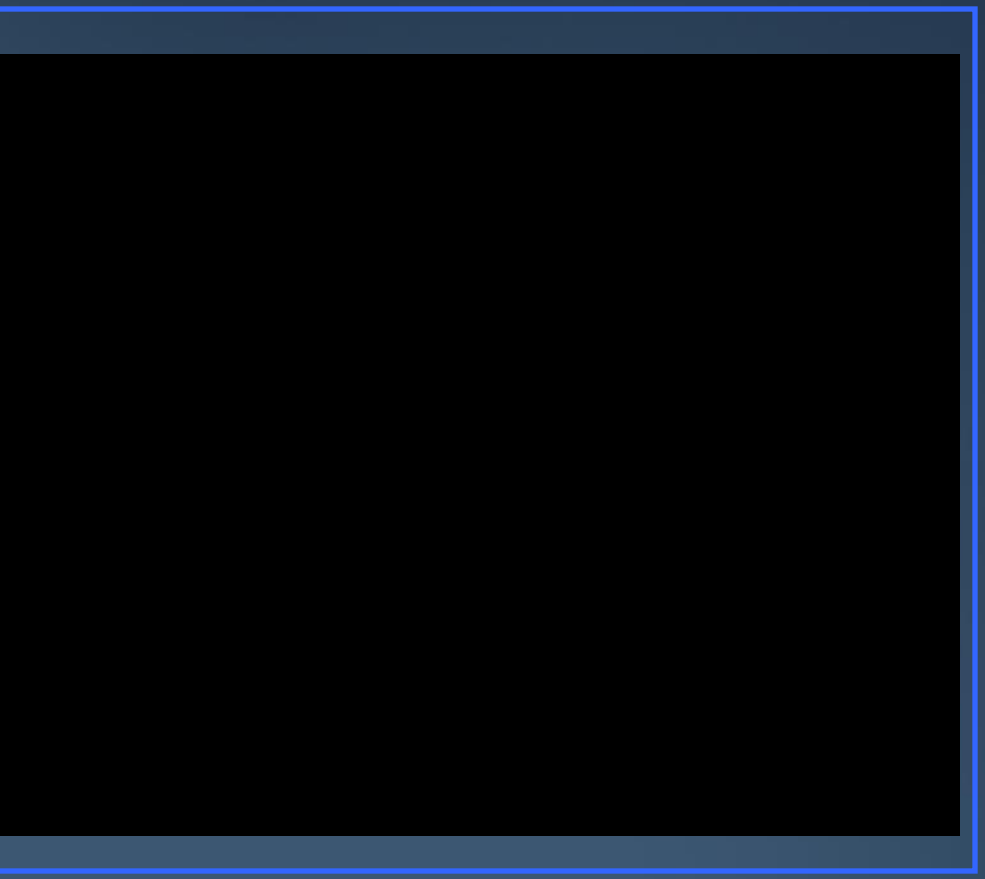
EHJ 2011

Bi-Caval Self-Expandable Valve Implantation

- „First in Man“

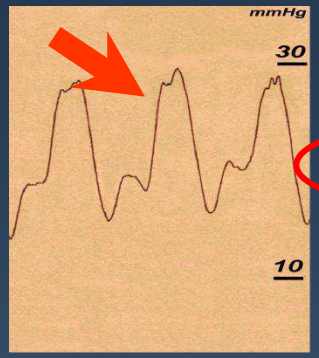
Patient: Clinical Presentation & Hemodynamics



- 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)

Patient: Clinical Presentation & Hemodynamics

SVC



v- wave: 27 mmHg

y-descent: 14 mmHg

Mean: 19mmHg

RA

v- wave: 32 mmHg

y-descent: 7 mmHg

Mean: 20mmHg

IVC

v- wave: 28 mmHg

y-descent: 15 mmHg

Mean: 19mmHg

- 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)
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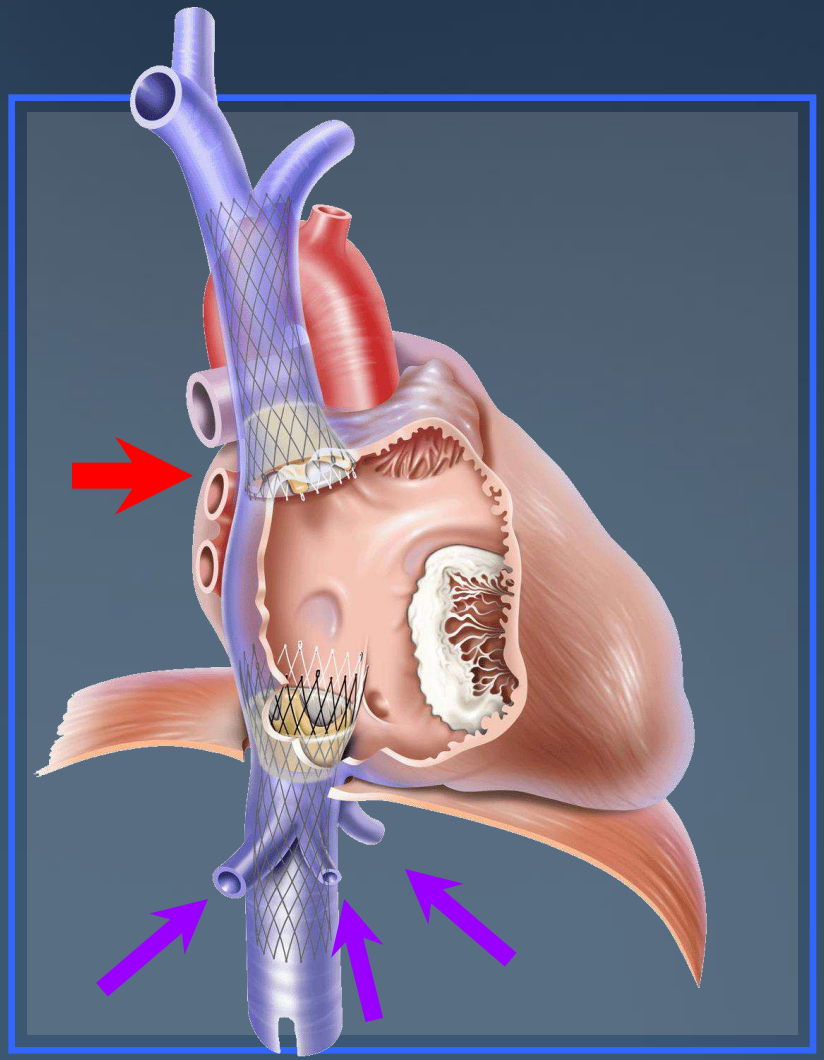
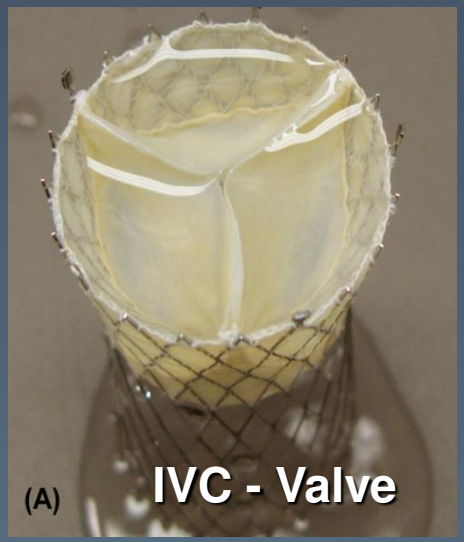
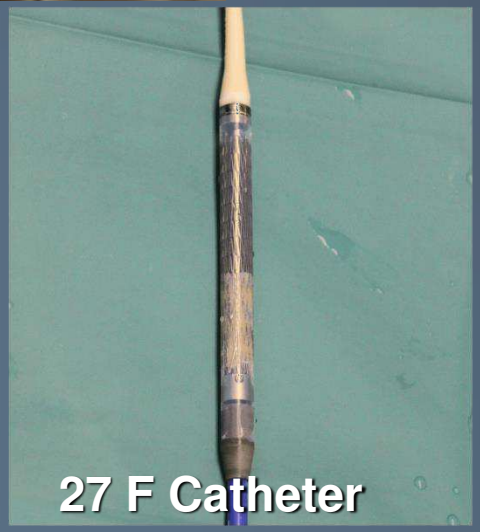
Interventional Concept – Transcatheter CAVI



- 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 trans-venous implantation

CAVI Procedure - Valve Deployment

- Loading and …
- Deployment of SVC-Valve
- Loading and …
- Deployment of IVC-Valve

Device Function: Transesophageal Echo

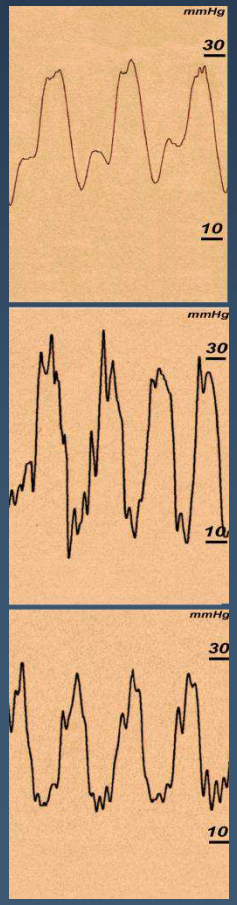
- immediate device function

  comfirmed by echo

Hemodynamic Changes after CAVI

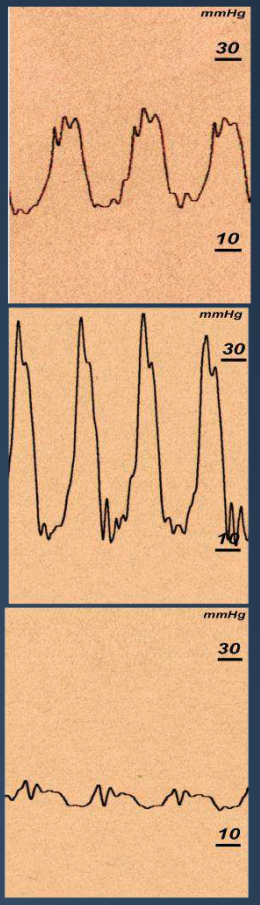
Before

	v-Wave
SVC	27mmHg
RA	32mmHg
IVC	28mmHg



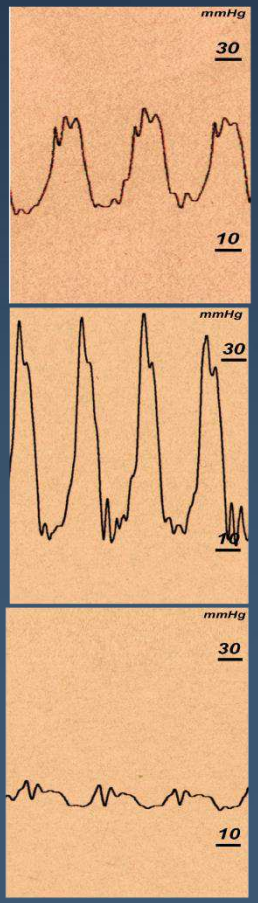
After

	v-Wave
SVC	21mmHg
RA	37mmHg
IVC	16mmHg



- … and improvement of invasive hemodynamics

Clinical Course After CAVI



y-wave

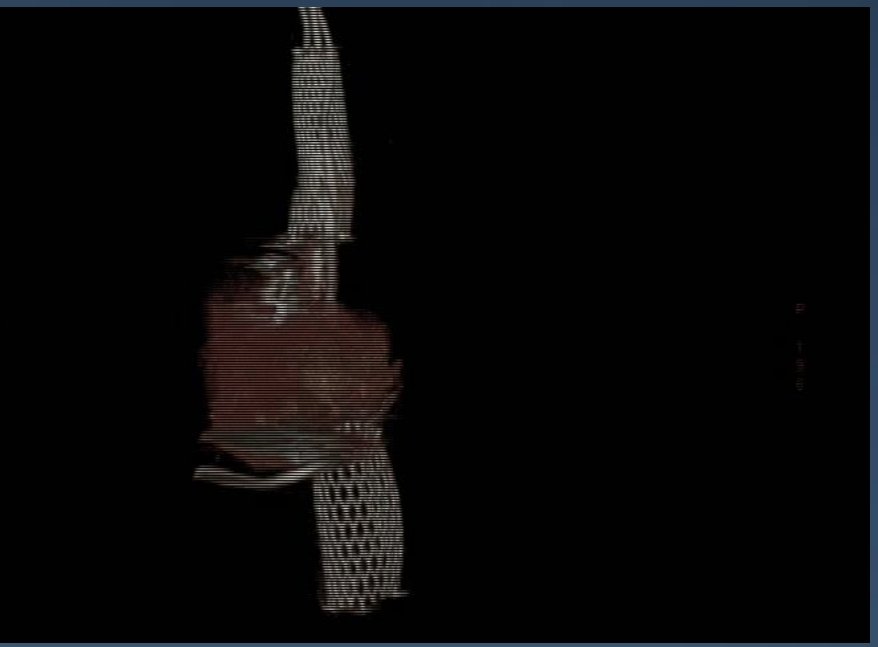
21mmHg

37mmHg

16mmHg

- uneventful recovery
- patient resumed off-bed acitvities 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 → 13/6mmHg
  - SVC: 27/14 mmHg → 21/7mmHg
- 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*

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- correct device position

d with fibrous

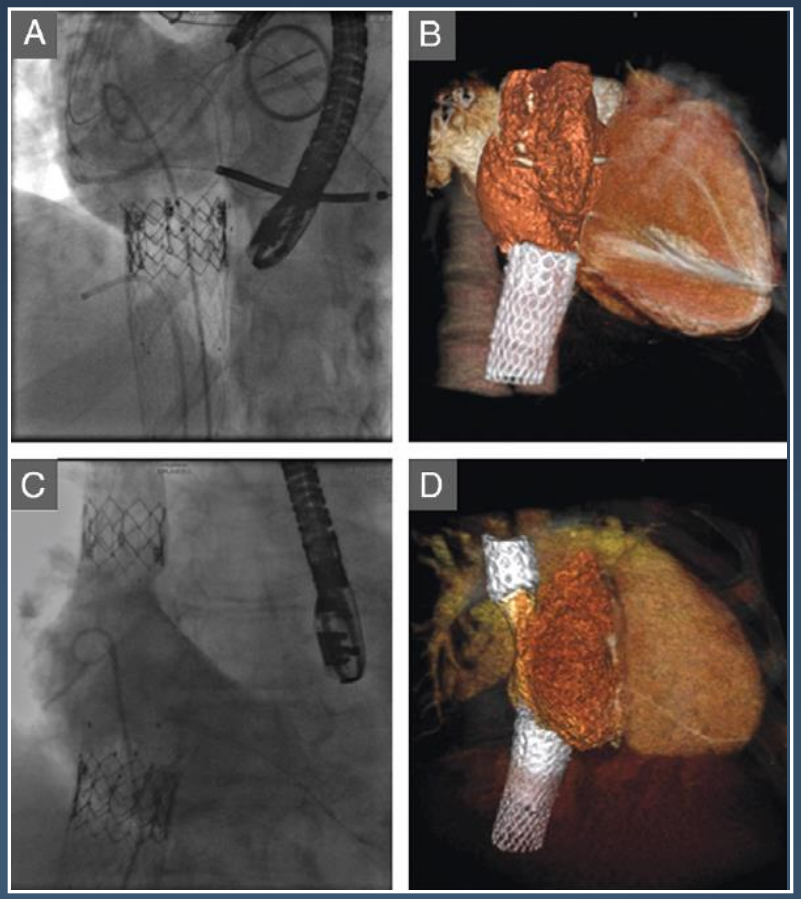
e device

hepatic veins

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 straight-forward 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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