TMVR repair and replace: A pathway on the horizon

Ralph Stephan von Bardeleben

Heart Center University Medicine Mainz
Structural Heart Disease and AV Valve Interventions
Current Management of Severe MR

Isolated MR (n=887)

Severe MR (n=540)

No Symptoms (n=144)

Symptoms (n=396)

No Intervention (n=193) 49%

Intervention (n=203) 51%

Prevalence

Age (years)

Decision not to operate

Decision to operate

P < 0.0001


www.escardio.org/guidelines
Role for interventional mitral valve therapy due to a increase in Valve disease morbidity of 270% in patients older than 75 years

Source: German Heart Report 2016 (German Heart Foundation - published January 2017)
Spectrum of Mitral Regurgitation

**Functional Mitral Regurgitation (FMR)**
- LV Dysfunction
  - Dilated Annulus
    - (Non-ischemic or ischemic dilated cardiomyopathy)
- LA Dysfunction
  - Dilated Annulus
    - (Chronic atrial fibrillation, hypertension)

**Etiologies**
- Advanced Barlow’s Disease
- Fibroelastic deficiency

**Leaflet prolapse due to:**
- Leaflet deformities or lesions
- Ruptured/ elongated chordae
- Papillary muscle rupture

**Loss of leaflet coapation due to:**
- Annular enlargement
- Papillary muscle displacement causing leaflet tethering/tenting

German Volume of TMVR passed surgical procedures in 2015: from „minority“ to „majority report“

Entwicklung der isolierten Mitralklappen chirurgie nach Operationsverfahren


Tc Mitral Valve Interventions: New Horizon?

The promise is Efficacy
The goal is Outcome
Mitral Valve Interventions: where is our Gold standard?

- Transcatheter Mitral valve procedures
- FMR more prevalent DMR
- Elderly patients with elevated comorbidities
- Post surgical repair
- Procedural EXPERIENCE is high
  TMVR has a fast learning curve
- Procedural SAFETY in repair high
  low procedural complications
- TMVreplacement is advancing slowly
Heart Surgery currently remains the Gold standard only for DMR patients
<table>
<thead>
<tr>
<th>Changes in recommendations</th>
<th>2012</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications for mitral valve intervention in secondary mitral regurgitation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>IIa C</strong></td>
<td>Surgery should be considered in patients with moderate secondary mitral regurgitation undergoing CABG</td>
<td>Taken out</td>
</tr>
<tr>
<td><strong>IIb C</strong></td>
<td>When revascularization is not indicated, surgery may be considered in patients with severe secondary mitral regurgitation and LVEF &gt;30%, who remain symptomatic despite optimal medical management (including CRT if indicated).</td>
<td><strong>IIb C (modified)</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>When revascularization is not indicated, surgery may be considered in patients with severe secondary mitral regurgitation and LVEF &gt;30%, who remain symptomatic despite optimal medical management (including CRT if indicated) and have a low surgical risk.</td>
</tr>
</tbody>
</table>
One-year outcomes and predictors of mortality after MitraClip therapy in contemporary clinical practice: results from the German transcatheter mitral valve interventions registry.
MitraClip Therapy
T.Feldman NEJM 2011

Technical Specs
Abbott Vasc
Transcatheter Mitral Valve Repair - STS/ACC TVT Registry (only 8.6% FMR, mean age 82 yrs)

Results – clinical outcomes at one year

- Either: 37.9%
- Death: 25.9%
- HF hospitalization: 20.2%
- Repeat Mitraclip = 6.2%
- MV surgery = 2.1%

Cumulative incidence (%)

Follow-up (months)

No. at risk
- 1867
- 1867
- 1867

<table>
<thead>
<tr>
<th>Follow-up (months)</th>
<th>0</th>
<th>2</th>
<th>4</th>
<th>6</th>
<th>8</th>
<th>10</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>1867</td>
<td>1867</td>
<td>1095</td>
<td>1095</td>
<td>1095</td>
<td>1095</td>
<td>1095</td>
<td>1095</td>
</tr>
<tr>
<td>1867</td>
<td>1293</td>
<td>889</td>
<td>889</td>
<td>889</td>
<td>889</td>
<td>889</td>
<td>889</td>
</tr>
<tr>
<td>1867</td>
<td>1095</td>
<td>723</td>
<td>723</td>
<td>723</td>
<td>723</td>
<td>723</td>
<td>723</td>
</tr>
</tbody>
</table>
Transcatheter Mitral Valve Repair - STS/ACC TVT Registry

Results – etiology of MR and outcome

Cumulative incidences

- Death
- Death/HF hosp

No. at risk for Death

<table>
<thead>
<tr>
<th>FMR</th>
<th>297</th>
<th>196</th>
<th>123</th>
<th>73</th>
<th>40</th>
</tr>
</thead>
<tbody>
<tr>
<td>DMR</td>
<td>1485</td>
<td>1024</td>
<td>726</td>
<td>472</td>
<td>287</td>
</tr>
</tbody>
</table>

Follow-up (months)

Cumulative incidences

- FMR
- DMR

P=0.002

P=0.028
Transcatheter Mitral Valve Repair - STS/ACC TVT Registry

Results – multi-variate models for 1-year mortality

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Hazard Ratio</th>
<th>Adjusted P values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (per 5 yrs)</td>
<td></td>
<td>0.005</td>
</tr>
<tr>
<td>Dialysis</td>
<td></td>
<td>0.004</td>
</tr>
<tr>
<td>Moderate or severe lung disease</td>
<td></td>
<td>0.02</td>
</tr>
<tr>
<td>LVEF (per 5%)</td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Severe TR</td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Residual MR=III/IV*</td>
<td></td>
<td>0.004</td>
</tr>
<tr>
<td>Residual MR=0/1*</td>
<td></td>
<td>0.005</td>
</tr>
</tbody>
</table>

*vs. Residual MR grade=2
Transcatheter Mitral Valve Repair – STS/ACC TVT Registry

Key points

- Acute procedural success in 92.8%, including in-hospital mortality of 2.7%
- At 1-year, mortality = 25.9%, HF hospitalization = 20.2%; either = 37.9%
- The one-year outcomes varied according to baseline characteristics and procedural results

Conclusions

- The study demonstrates acute effectiveness and safety of transcatheter MV repair in the U.S
- A subset of these inoperable or high-risk patients have mortality or heart-failure rehospitalization by one year
- Certain clinical variables (age, LVEF, severe TR, lung disease, dialysis) and the degree of MR reduction are significant predictors of these long-term clinical outcomes
# Morphology for a MitraClip therapy

<table>
<thead>
<tr>
<th>Optimal valve morphology</th>
<th>Conditionally suitable valve morphology</th>
<th>Unsuitable valve morphology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central pathology in Segment 2</td>
<td>Pathology in Segment 1 or 3</td>
<td>Perforated mitral valve leaflet or cleft</td>
</tr>
<tr>
<td>No leaflet calcification</td>
<td>Mild calcification outside of the grip-zone of the clip system; ring calcification, post annuloplasty</td>
<td>Severe calcification in the grip-zone</td>
</tr>
<tr>
<td>Mitral valve opening area &gt;4 cm²</td>
<td>Mitral valve opening area ≥3 cm² with good residual mobility</td>
<td>Haemodynamically significant mitral stenosis (valve opening area &lt;3 cm², MPGe ≥5 mmHg)</td>
</tr>
<tr>
<td>Mobile length of the posterior leaflet ≥10 mm</td>
<td>Mobile length of the posterior leaflet 7–10 mm</td>
<td>Mobile length of the posterior leaflet &lt;7 mm</td>
</tr>
<tr>
<td>Coaption depth &lt;11 mm</td>
<td>Coaption depth ≥11 mm</td>
<td></td>
</tr>
<tr>
<td>Normal leaflet strength and mobility</td>
<td>Leaflet restriction in systole (Carpentier IIIB)</td>
<td>Rheumatic leaflet thickening and restriction in systole and diastole (Carpentier IIIA)</td>
</tr>
<tr>
<td>Flail-width &lt;15 mm Flail-Gap &lt;10 mm</td>
<td>Flail-width &gt;15 mm only with a large ring width and the option for multiple clips</td>
<td>Barlow’s syndrome with multisegment flail leaflets</td>
</tr>
</tbody>
</table>

# Indications for the MitraClip therapy

<table>
<thead>
<tr>
<th>Ideal for Mitralclip treatment</th>
<th>MitraClip to be considered</th>
<th>MitraClip not recommended or only in exceptional cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe mitral regurgitation and Optimal valve morphology and FMR with LVEF&lt;30 % or DMR (with operation-indication following guidelines) and A high operative risk or other risk-constellations</td>
<td>Moderate to severe mitral regurgitation and Optimal valve morphology and FMR or DMR (with operation-indication following guidelines) and High operative risk, very high age or other risk-constellations</td>
<td>Moderate to severe mitral regurgitation and Conditionally suitable valve morphology or Life expectancy &lt;12 months or LVEF&lt;15% or cardiothoracic operation planned due to other indications or Previously operated mitral valve or As surgical/interventional hybrid procedure or At low operative risk</td>
</tr>
</tbody>
</table>
## Device and Procedure Time

<table>
<thead>
<tr>
<th></th>
<th>MitraClip (N=2175)</th>
<th>MitraClip NT (N=1002)</th>
<th>Total (N=3177)</th>
<th>P-Value¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure Duration (min)¹</td>
<td>154.3 ± 77.3 (2175)</td>
<td>136.2 ± 69.0 (1002)</td>
<td>148.6 ± 75.2 (3177)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Total Device Time (min)²</td>
<td>61.4 ± 57.8 (2157)</td>
<td>54.8 ± 39.7 (999)</td>
<td>59.3 ± 52.8 (3156)</td>
<td>0.0002</td>
</tr>
</tbody>
</table>

Source: Abbott data on file (April 10, 2017 (10:15))

¹ Procedure Time is measured from the time of the Anaesthesia Induction to the time of Anaesthesia Discontinuation

² Device Time is measured from the time of insertion of the Steerable Guide Catheter to the time the MitraClip Delivery Catheter is retracted into the Steerable Guide Catheter

---

1. From t-test for continuous variables and Chi-square test for binary variables.
   Note: All p-values displayed are two-tailed and not from pre-specified hypothesis testing and are displayed for information only.
   Note: N is the total number of subjects.
One-year outcomes and predictors of mortality after MitraClip therapy in contemporary clinical practice: results from the German transcatheter mitral valve interventions registry

Miriam Puls¹*, Edith Lubos², Peter Boekstegers³, Ralph Stephan von Bardeleben⁴, Taoufik Ouarrak⁵, Christian Butter⁶, Christine S. Zuern⁷, Raffi Bekeredjian⁸, Horst Sievert⁹, Georg Nickenig¹⁰, Holger Eggbrecht¹¹, Jochen Senges⁵†, and Wolfgang Schillinger¹,¹²†

¹Herzzentrum, Georg-August-Universität Göttingen, Göttingen, Germany; ²Universitäres Herzzentrum Eppendorf Hamburg, Hamburg, Germany; ³Klinikum Siegburg (Kardiologie und Angiologie), Siegburg, Germany; ⁴Universitätsmedizin Mainz, 2. Med. Klinik, Mainz, Germany; ⁵Stiftung Institut für Herzinfarktforschung, Ludwigshafen, Germany; ⁶Herzzentrum Brandenburg, Bernau, Germany; ⁷Universitätsklinikum Tübingen, Tübingen, Germany; ⁸Universitätsklinikum Heidelberg, Heidelberg, Germany; ⁹Cardio Vasculaires Centrum (CVC) Frankfurt St. Katharinen, Frankfurt am Main, Germany; ¹⁰Universitätsklinikum Bonn (Med. Klinik und Poliklinik II), Bonn, Germany; ¹¹Cardioangiologisches Centrum Bethanien (CCB), Frankfurt am Main, Germany; and ¹²Helios Albert-Schweitzer-Klinik Northeim, Northeim, Germany
Success rate MitraClip went up from 77% to 97%.

Surgical intervention within 1 year dropped from 21% EVEREST 2009 to 0.9 or 2.3% ACESS/TRAMI 2013.

### Table 2: In-hospital/30 days outcomes after MitraClip implantation in different registries and trials

<table>
<thead>
<tr>
<th></th>
<th>EVEREST II (n = 184)</th>
<th>ACESS-EU (n = 567)</th>
<th>Transcatheter Valve Treatment Sentinel Pilot Registry (n = 628)</th>
<th>TRAMI (prospective cohort) (n = 749)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital stay (days)</td>
<td>NA</td>
<td>7.7 ± 8.2 (median: 6.0)</td>
<td>5.0 [3.0−7.0]</td>
<td>9.0 [6.0−15.0]</td>
</tr>
<tr>
<td>Procedural success</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Clip implanted + MR ≤ 2+/not severe)</td>
<td>137/178 (77.0%)</td>
<td>516/567 (91.0%)</td>
<td>599/628 (95.4%)</td>
<td>719/741 (97.0%)</td>
</tr>
<tr>
<td>Mitral regurgitation at discharge, n (%)</td>
<td>NA</td>
<td>NA</td>
<td>268/368 (72.8%)</td>
<td>631/741 (85.2%)</td>
</tr>
<tr>
<td>None/mild</td>
<td>NA</td>
<td>NA</td>
<td>82/268 (30.2%)</td>
<td>82/741 (11.6%)</td>
</tr>
<tr>
<td>Moderate</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Step 1</td>
<td>NA</td>
<td>NA</td>
<td>17/444 (3.8%)</td>
<td>37/436 (8.5%)</td>
</tr>
<tr>
<td>Additional MV procedure, n (%)</td>
<td>37/181 (21%)</td>
<td>55/567 (9.7%)</td>
<td>17/444 (3.8%)</td>
<td>37/436 (8.5%)</td>
</tr>
<tr>
<td>Surgical</td>
<td>37/181 (21%)</td>
<td>36/567 (6.3%)</td>
<td>4/444 (0.9%)</td>
<td>10/436 (2.3%)</td>
</tr>
<tr>
<td>Percutaneous</td>
<td>0/181 (0%)</td>
<td>19/567 (3.4%)</td>
<td>13/444 (2.9%)</td>
<td>23/436 (5.2%)</td>
</tr>
</tbody>
</table>

### Table 3: One-year outcomes after MitraClip implantation in different registries and trials

<table>
<thead>
<tr>
<th></th>
<th>EVEREST II (n = 184)</th>
<th>ACESS-EU (n = 567)</th>
<th>Transcatheter Valve Treatment Sentinel Pilot Registry European Sentinel Pilot Registry (n = 552/628)</th>
<th>TRAMI (prospective cohort) (n = 749)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rehospitalizations, n (%)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>364/566 (64.3%)</td>
</tr>
<tr>
<td>Cardiac decompensation</td>
<td>NA</td>
<td>NA</td>
<td>22.8% (Kaplan–Meier curve)</td>
<td>80/566 (14.1%)</td>
</tr>
<tr>
<td>Other cardiac reason</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>101/566 (17.8%)</td>
</tr>
<tr>
<td>Non-cardiac reason</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>146/566 (25.8%)</td>
</tr>
<tr>
<td>Additional MV procedure, n (%)</td>
<td>37/181 (21%)</td>
<td>55/567 (9.7%)</td>
<td>17/444 (3.8%)</td>
<td>37/436 (8.5%)</td>
</tr>
<tr>
<td>Surgical</td>
<td>37/181 (21%)</td>
<td>36/567 (6.3%)</td>
<td>4/444 (0.9%)</td>
<td>10/436 (2.3%)</td>
</tr>
<tr>
<td>Percutaneous</td>
<td>0/181 (0%)</td>
<td>19/567 (3.4%)</td>
<td>13/444 (2.9%)</td>
<td>23/436 (5.2%)</td>
</tr>
</tbody>
</table>
Can we use a **Toolbox** for interventional repair?

- **2007**: MitraClip (eValve) Abbott
- **2008**: MitraClip Abbott
- **2009**: CARILLON Mitral Contour System Cardiac Dimensions (February)
- **2010**: Enhanced CARILLON Mitral Contour System Cardiac Dimensions (September)
- **2011**: NeoChord (January)
- **2012**: Cardioband Valtech (September)
- **2013**: Mitralign (February)
- **2014**: MitraClip NT Abbott
- **2015**: Mitralign (February)
- **2016**: MitraClip NT Abbott

*Court. C. Grasso*
Hybrid OR integration of multimodality images in VHD
First combination of Cardioband and MitraClip NT
Mainz May 2016
COMBO Case 2: transcath Surgical Approach Alfieri central & medial with TcAnnuloplasty
von Bardeleben RS, Schulz E; European Heart Journal 2017

64 yo female after failure of surgical SMVR

Physio II 28 mm Sapien 3 in Ring using Heart Navigator 3.0
TMVR in Native MAC

- 64 patients at 32 centers
- STS 14.4%
- Success in 72%
- Complications in 20%
  - LVOT obstruction (9%)
  - Valve embolization (6%)
  - Stroke (7%)
  - Conversion to surgery (6%)
- 30-day mortality 30%

Guerrero et al, JACC Intv 2016;9:1361-71
Transcatheter Mitral Valve Replacement for Patients With Symptomatic Mitral Regurgitation: A Global Feasibility Trial

ABSTRACT

BACKGROUND: Symptomatic mitral regurgitation (MR) is associated with high morbidity and mortality, and can be exacerbated by surgical valve repair or replacement. Despite this, many patients with MR do not undergo surgery. Transcatheter mitral valve replacement (TMVR) may be an option for selected patients with severe MR.

OBJECTIVES: This study aimed to assess the feasibility and safety of TMVR in a cohort of patients with native valve MR who were at high risk for cardiac surgery.

METHODS: Patients underwent transcatheter, transapical delivery of a self-expanding mitral valve prosthesis and were examined in a prospective registry for short- and long-term outcomes.

RESULTS: Thirty patients (age 66 ± 11 years; 25 men; with grade II or III MR) underwent TMVR. The MR etiology was secondary (n = 23), primary (n = 4), or mixed pathology (n = 3). The Society of Thoracic Surgeons Predicted Risk of Mortality was 33% ± 17%. There were no acute death, strokes, or myocardial infarctions. One patient died 33 days after TMVR from hospital-acquired pneumonia. Postoperative left ventricular function was preserved in patients at follow-up and resolved after increased oral anticoagulation with warfarin. At 30 days, transthoracic echocardiography revealed mitral regurgitation of grade I in 1 patient, and no residual MR in the remaining 27 patients with valves in situ. The left ventricular end-diastolic volume index decreased (90.1 ± 24.2 mL/m² at baseline vs. 72.1 ± 19.3 mL/m² at follow-up; p = 0.0012), as did the left ventricular end-systolic volume index (64.8 ± 44.1 mL/m² vs. 48.1 ± 16.3 mL/m²; p = 0.019). Twenty-five percent of the patients reported mild or no symptoms of heart failure (New York Heart Association Functional Class I or II). Successful device implantation was confirmed by angiographic studies, and device malfunction at 30 days was 0.0%. There were no residual MRs at echocardiograms during follow-up.

CONCLUSIONS: TMVR is an effective and safe therapy for selected patients with symptomatic MR. Further evaluation of TMVR using prostheses specifically designed for the mitral valve is warranted. These interventions may help address unmet needs in patients at high risk for surgery.
Editorial TMVR

German BfARM approval last week for ce study in TMVR

Transcatheter Mitral Valve Replacement: Nears the First Hurdle*

Howard C. Herrman, MD, Randolph Chitwood, Jr., MD

These short-term results can be considered remarkable and contrast with case reports of other first-generation devices having worse outcomes.

The multidisciplinary heart team, now established as a Class I indication for the evaluation of complex patients with valvular heart disease, should play a central role in the use of this new technology. This study demonstrates the impressive progress that has occurred in transcatheter mitral valve therapy and sets a high bar for competing technology, but it is only the first hurdle. The opportunity for cardiologists and surgeons to learn from each other, practice together, and improve patient outcomes makes us confident that together we will be able to clear the remaining hurdles in front of us.
US EFS trials for TMVR

CardiAQ-Edwards  Tiara (Neovasc)

Tendyne (Abbott)  Twelve (Medtronic)
# Tendyne TC Mitral Valve

**Low PVL rate - Low Mortality, Around 100 patients treated – data to be presented at TCT Denver 2017**

<table>
<thead>
<tr>
<th>Tendyne Device</th>
<th>![Image of valve]</th>
</tr>
</thead>
<tbody>
<tr>
<td>• D-Shaped Self-Expanding Nitinol Outer Frame</td>
<td></td>
</tr>
<tr>
<td>• Designed to Conform to Native MV Anatomy</td>
<td></td>
</tr>
<tr>
<td>• Circular Self-Expanding Nitinol Inner Frame</td>
<td></td>
</tr>
<tr>
<td>• Large Effective Orifice Area (&gt;3.0cm²)</td>
<td></td>
</tr>
<tr>
<td>• Larger EOA than any Surgical Valve</td>
<td></td>
</tr>
<tr>
<td>• Porcine Pericardial Tri-Leaflet Valve</td>
<td></td>
</tr>
<tr>
<td>• Large Valve Size Matrix to Treat Varying Anatomies</td>
<td></td>
</tr>
<tr>
<td>• Outer Frame Sizes: 30-43mm AP x 34-50mm CC</td>
<td></td>
</tr>
<tr>
<td>• Valve Tether to Apex</td>
<td></td>
</tr>
<tr>
<td>• Provides Valve Stability - Designed to Reduce PVL</td>
<td></td>
</tr>
<tr>
<td>• Apical Pad Assists in Access Closure</td>
<td></td>
</tr>
</tbody>
</table>

Tendyne product is currently in development at Abbott. Neither approved or available for sale.
Patient 003-C001
- 75y.o. Male
- Severe Degenerative MR
- Prior CABG, CKD
  - (eGFR 20 ml/kg/min)
TMVR in severe FMR:
Early Feasibility Study - November 2014

Patient 004-E001
- 76 y.o. Male
- Mod/Severe FMR with EF 40%
- Hx of MI with prior CABG
- HTN and Type II DM
- Chronic Pulmonary Disease

Images courtesy of David Muller, St. Vincent’s Hospital

Tendyne product is currently in development at Abbott. Neither approved or available for sale.
TMVR
3D Echo EnFace View

Image courtesy of N. Moat, A. Duncan, Royal Brompton Hospital

Tendyne product is currently in development at Abbott. Neither approved or available for sale.
Three-chamber view of the heart and implanted valve shows the valve, left ventricular outflow tract, and tether placement.

Image courtesy of D- Muller, St Vincent’s Hospital

Tendyne product is currently in development at Abbott. Neither approved or available for sale.
Short-axis view of the atrial surface of the mitral valve, viewed from the left atrium. The self-expanding outer frame seats the prosthesis within the mitral annulus. The cuff of the outer frame lies on the floor of the annulus and abuts the aortomitral curtain anteriorly. The valve leaflets are attached to a circular inner frame.

Image courtesy of D- Muller, St Vincent’s Hospital

Tendyne product is currently in development at Abbott. Neither approved or available for sale.
## Tendyne TMVI: D30 Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>N=30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death (all cause)</td>
<td>1 (3.3%)</td>
</tr>
<tr>
<td>Cardiac</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Non-cardiac</td>
<td>1 (3.3%)</td>
</tr>
<tr>
<td>CVA</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>MV surgery</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Re-hospitalisation</td>
<td></td>
</tr>
<tr>
<td>Heart failure</td>
<td>4 (13.8%)</td>
</tr>
<tr>
<td>LVAD/transplant</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Other (ileus)</td>
<td>1 (3.3%)</td>
</tr>
<tr>
<td>Device-related</td>
<td></td>
</tr>
<tr>
<td>Hemolysis, transfusion</td>
<td>1 (3.3%)</td>
</tr>
<tr>
<td>Leaflet thrombosis</td>
<td>1 (3.3%)</td>
</tr>
</tbody>
</table>

D. Muller, TCT 2016

Tendyne product is currently in development at Abbott. Neither approved or available for sale.
MR severity post-TMVI (n=30)
Efficacy MR 0 is high

<table>
<thead>
<tr>
<th>Grade</th>
<th>Baseline</th>
<th>30 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade IV</td>
<td>93.1</td>
<td>6.7*</td>
</tr>
<tr>
<td>Grade III</td>
<td>6.9</td>
<td>3.3</td>
</tr>
<tr>
<td>Grade II</td>
<td>90.0</td>
<td></td>
</tr>
<tr>
<td>Grade I</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*No device in situ (n=2)

Tendyne product is currently in development at Abbott. Neither approved or available for sale.
LV Volume post-TMVI (n=30) consistent remodeling

LV End-Diastolic Volume Index (mls/m²)

Baseline  Day 30

P=0.0012

D. Muller, TCT 2016

Tendyne product is currently in development at Abbott. Neither approved or available for sale.
A patient-centric approach

UNDERTREATED POPULATIONS

ACROSS AORTIC, TRICUSPID, AND MITRAL


Information contained herein for PRESENTATION outside of the U.S. ONLY. Not to be reproduced, distributed or excerpted. Check the regulatory status of the device in areas where CE marking is not the regulation in force. © 2017 Abbott. All rights reserved. 9-EH-4-6867-01 05-2017
TMVR: the new horizon

- There is a growing ageing population 65+ in the US, in Europe, UK and China
- TMVrepair is safe, versatile and available
- The Toolbox and COMBO concept of different devices for specific anatomies is evolving
- TMVreplacement is slowly advancing with superior efficacy but still some limitations in patient eligibility
- Modern 3D Imaging is a „must“ in TMVR
TMVR: the new horizon

„The Future of .. Heart Valve treatment is percutaneous“

Michael Borger, MD PhD
Director Heart Surgery
Heart Center Leipzig

Source: extracted from an Interview September 2017 on German Television mdr healthchannel „Hauptsache gesund“
Thank you

heartvalves@unimedizin-mainz.de
stephan.von_bardeleben@unimedizin-mainz.de