VIVID meeting
TCT 2018
Outline of the meeting

• 11:00-11:15 AM: Introduction and update on recent publications – Danny Dvir, MD

• 11:15-11:30 AM: VIVID SVD Definitions – Philippe Pibarot DVM, PhD

• 11:30 AM-12:00: Bioprosthetic Valve Ring Fracture (BVF): Current Data – Keith Allen, MD

• 12:00-12:15 PM: PM Mitral ViV/ViR Extended Analysis & Suggestions for Subanalyses - Henrique Ribeiro, MD

• 12:15-12:30 PM: International BVF Registry and future directions – Adnan Chhatriwalla, MD

• 12:30-13:00 PM: VIVID Calculator – Liron Tzemach

• 13:00-13:15 PM: SAPIEN 3 Positioning in ViV – Matheus Simonato

• 13:15-13:45 PM: Transcatheter Laceration to Prevent Coronary Obstruction (BASILICA) – Jaffar Khan, MD & Danny Dvir, MD

• 13:45-14:00 PM: Final discussion on future projects and adjourn
Recent publications and submissions
Transcatheter Replacement of Failed Bioprosthetic Valves

Large Multicenter Assessment of the Effect of Implantation Depth on Hemodynamics After Aortic Valve-in-Valve

Matheus Simonato; John Webb, MD; Ran Kornowski, MD; Alec Vahanian, MD; Christian Frerker, MD; Henrik Nissen, MD; Sabine Bleiziffer, MD; Alison Duncan, MD; Josep Rodés-Cabau, MD; Guilherme F. Attizzani, MD; Eric Horlick, MD; Azeem Latib, MD; Raffi Bekeredjian, MD; Marco Barbanti, MD; Thierry Lefevre, MD; Alfredo Cerrillo, MD; José María Hernández, MD; Giuseppe Bruschi, MD; Konstantinos Spargias, MD; Alessandro Iadanza, MD; Stephen Brecker, MD; José Honório Palma, MD; Ariel Finkelstein, MD; Mohamed Abdel-Wahab, MD; Pedro Lemos, MD; Anna Sonia Petronio, MD; Didier Champagnac, MD; Jan-Malte Sinning, MD; Stefano Salizzoni, MD; Massimo Napodano, MD; Claudia Fiorina, MD; Antonio Marzocchi, MD; Martin Leon, MD; Danny Dvir, MD
Median Implantation Depth: 8.57mm (IQR 5.7mm – 11.4mm)

Implantation Depth and Gradients

Median Implantation Depth: 8.57mm (IQR 5.7mm – 11.4mm)
Multivariate Analysis
Elevated Post-Procedural Mean Gradients

- High Implantation (vs. low)  \( p < 0.001 \)
- CoreValve use (vs. SAPIEN XT)  \( p = 0.02 \)
- Male sex (vs. Female)  \( p = 0.11 \)
- Age (yrs.)  \( p = 0.09 \)
- Left ventricular ejection fraction (%)  \( p = 0.63 \)
- Small surgical valve (vs. larger valves)  \( p = 0.29 \)
- Stenosis and mixed failure (vs. regurgitation)  \( p = 0.002 \)

In vitro evaluation of implantation depth in valve-in-valve using different transcatheter heart valves


This paper also includes supplementary data published online at: http://www.jcmi.org/content/16/4/99

Keywords
- aortic valve replacement
- circulatory in vitro studies

Abstract
Aims: Transcatheter heart valve (THV) implantation in failed bioprosthetic valves (valve-in-valve [ViV]) offers an alternative therapy for high-risk patients. Elevated post-procedural gradients are a significant limitation of aortic ViV. Our objective was to assess the relationship between depth of implantation and hemodynamics.

Methods and results: Commercially available THVs used for ViV were included in the analysis.
CoreValve Evolut In-Vitro Assessment

CoreValve Evolut 23mm in Epic 19mm

High implantation results larger EOA

Effect of transcatheter aortic valve size and position on valve-in-valve hemodynamics: An in vitro study

Ali N. Azadani, PhD, Michael Reardon, MD, Matheus Simonato, Gabriel Aldea, MD, Georg Nickenig, MD, Ran Kornowski, MD, and Danny Dvir, MD

ABSTRACT

Objective: Transcatheter heart valve implantation in failed aortic bioprostheses (valve-in-valve [ViV]) is an increasingly used therapeutic option for high-risk patients. However, high postprocedural gradients are a significant limitation of aortic ViV. Our objective was to evaluate Medtronic CoreValve Evolut R ViV hemodynamics in relation to the degree of device oversizing and depth of implantation.

Methods: Evolut R devices of 23 and 26 mm were implanted within 21-, 23-, and 25-mm Hancock II bioprostheses. Small and gradual changes in implantation
FIGURE 6. Mean pressure gradient ratio of 26-mm and 23-mm CoreValve Evolut R versus the true internal diameter of the surgical bioprostheses.
Structural Heart Disease

Matched Comparison of Self-Expanding Transcatheter Heart Valves for the Treatment of Failed Aortic Surgical Bioprosthesis

Insights From the Valve-in-Valve International Data Registry (VIVID)

Sami Alnasser, MD; Asim N. Cheema, MD; Matheus Simonato; Marco Barbanti, MD; Jeremy Edwards, MD; Ran Kornowski, MD; Eric Horlick, MD; Harindra C. Wijeyasurya, MD; Luca Testa, MD, PhD; Francesco Bedogni, MD; Hafid Amrane, MD; Thomas Walthier, MD; Marc Pelletier, MD; Azeem Latib, MD; Jean-Claude Laborde, MD; David Hildick-Smith, MD; Won-Keun Kim, MD; Didier Tchetche, MD; Marco Agrifoglio, MD; Jan-Malte Sinning, MD; Ad J. van Boven, MD; Joëlle Kefer, MD; Christian Freker, MD; Nicolas M. van Mieghem, MD, PhD; Axel Linke, MD; Stephen Worthley, MD; Anita Asgar, MD; Carmelo Sgroi, MD; Mina Aziz, MD; Haim D. Danenberg, MD; Marino Labianca, MD; Ganesh Manoharan, MD; Anson Cheung, MD; John G. Webb, MD; Danny Dvir, MD; for the Valve-in-Valve International Data Registry Investigators
Self-expandable THV for VinV

1:2 matching

n=54
Portico™

n=108
CoreValve®

Alnasser S. et al. VIVID Registry. Circ Cardiovasc Interv. 2017
Self-expandable THV for VinV

A cluster of significant AR after Portico aortic valve-in-valve

Alnasser S. et al. VIVID Registry. Circ Cardiovasc Interv. 2017
Self-expandable THV for VinV

Significant mortality difference that was not associated with AR post viv

Alnasser S. et al. VIVID Registry. Circ Cardiovasc Interv. 2017
Matched comparison of next- and early-generation balloon-expandable transcatheter heart valve implantations in failed surgical aortic bioprostheses

Moritz Seiffert¹, MD; Hendrik Treede², MD; Joachim Schofer³, MD; Axel Linke⁴, MD; Jochen Wöhrle⁵, MD; Hardy Baumbach⁶, MD; Julinda Mehilli⁷, MD; Vinayak Bapat⁸, MD; Matheus Simonato⁹, MD; Thomas Walther¹⁰, MD; Mathias Kullmer¹¹, MD; Peter Boekstegers¹², MD; Stephan Ensminger¹³, MD; Thomas Kurz¹⁴, MD; Helene Elchaninoff¹⁵, MD; Ardawan Rastan¹⁶, MD; Nicolas Werner¹⁷, MD; Ared de Weger¹⁸, MD; Christian Frerker¹⁹, MD; Bernward Lauer²⁰, MD; Olivier Muller²¹, MD; Brian Whisenant²², MD; Arun Thukkani²³, MD; Giora Weisz²⁴, MD; Danny Dvir²⁵, MD
OBJECTIVE:
Evaluation of safety and efficacy of VinV with SAPIEN 3 vs. SAPIEN XT for the treatment of degenerated aortic surgical bioprostheses
SAPIEN 3 23 mm in PERIMOUNT 21 mm

<table>
<thead>
<tr>
<th>Low implant</th>
<th>High implant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depth: 36%</td>
<td>Depth: 15.5%</td>
</tr>
<tr>
<td>Mean gradient: 35 mmHg</td>
<td>Mean gradient: 18 mmHg</td>
</tr>
</tbody>
</table>
Elevated gradients after VinV in small surgical valves (True ID ≤21 mm) with both SAPIEN 3 and SAPIEN XT.
Impact of Pre-Existing Prosthesis-Patient Mismatch on Survival Following Aortic Valve-in-Valve Procedures

Philippe Pibarot, DVM, PhD, a Matheus Simonato, b Marco Barbanti, MD, c Axel Linke, MD, d Ran Kornowski, MD, e Tanja Rudolph, MD, f Mark Spence, MB, BCH, g Neil Moat, MBBS, MS, h Gabriel Aldea, MD, i Marco Mennuni, MD, j Alessandro Iadananza, MD, k Hafid Amrane, MD, l Diego Gaia, MD, PhD, b Won-Keun Kim, MD, m Massimo Napodano, MD, n Hardy Baumbach, MD, o Ariel Finkelstein, MD, p Junjiro Kobayashi, MD, Ph. D, q Stephen Brecker, MD, r Creighton Don, MD, PhD, s Alfredo Cerillo, MD, t Axel Unbehaun, MD, u David Attias, MD, v Mohammed Nejjari, MD, w Noah Jones, MD, x Claudia Fiorina, MD, y Didier Tchetch, MD, z Raphael Philippart, MD, a Konstantinos Spargias, MD, y Jose-Maria Hernandez, MD, PhD, z Azeem Latib, MD, aa Danny Dvir, MD b
Study Flowchart

Aortic ViV cases of the VIVID Registry (n = 1,168)

- No PPM (n = 495) 42.3%
- Any PPM (n = 673) 57.6%
  - Moderate PPM (n = 584) 50%
  - Severe PPM (n = 89) 7.6%

Mean age: 78.6 ± 8.4 years; STS: 9.9% ± 8.7%

Pibarot P, et al. VIVID Registry JACCInt (in press)
FIGURE 1 Rates of Elevated Post-Procedural Transvalvular Gradients and 30-Day and 1-Year Mortality According to Pre-Existing Severe Prosthesis-Patient Mismatch

Rates of elevated (≥20 mm Hg) post-procedural gradients, 30-day mortality, and unadjusted 1-year mortality according to presence or absence of pre-existing severe prosthesis-patient mismatch (PPM).

Pibarot P, et al. VIVID Registry JACCInt (in press)
Rates of elevated (≥20 mm Hg) post-procedural gradients, 30-day mortality, and 1-year mortality according to presence or absence of pre-existing severe prosthesis-patient mismatch (PPM) and to the type of transcatheter heart valve (i.e., self-expanding CoreValve or Evolut vs. balloon-expandable SAPIEN) used for valve-in-valve implantation.

Pibarot P, et al. VIVID Registry JACCInt (in press)
Pibarot P, et al. VIVID Registry JACCInt (in press)

**Hazard Ratio (95% CI) vs. HR**

- **Severe PPM**
  - HR 1.88 (95% CI 1.07 - 3.28)  \( p = 0.03 \)

- **Stentless Surgical Valve**
  - HR 1.7 (95% CI 0.96 - 3.03)  \( p = 0.07 \)

- **Renal Failure**
  - HR 1.34 (95% CI 0.91 - 1.98)  \( p = 0.14 \)

- **Diabetes Mellitus**
  - HR 1.14 (95% CI 0.76 - 1.7)  \( p = 0.53 \)

- **STS Score (%)**
  - HR 1.05 (95% CI 1.03 - 1.06)  \( p < 0.001 \)

- **Label Size (mm)**
  - HR 0.91 (95% CI 0.82 - 1)  \( p = 0.06 \)
Severe PPM of the surgical valves is associated with higher mortality after ViV

HR 1.86 (CI 95% 1.07 - 3.28)  
\( p = 0.03 \)

Pibarot P, et al. VIVID Registry JACCInt (in press)
Incidence, predictors, and clinical outcomes of coronary obstruction following transcatheter aortic valve replacement for degenerative bioprosthetic surgical valves: insights from the VIVID registry

Henrique B. Ribeiro\textsuperscript{1,2}, Josep Rodés-Cabau\textsuperscript{1*}, Philipp Blanke\textsuperscript{3}, Jonathon Leipsic\textsuperscript{3}, Jong Kwan Park\textsuperscript{3}, Vinayak Bapat\textsuperscript{4}, Raj Makkar\textsuperscript{5}, Matheus Simonato\textsuperscript{3,6}, Marco Barbanti\textsuperscript{7}, Joachim Schofer\textsuperscript{8}, Sabine Bleiziffer\textsuperscript{9}, Azeem Latib\textsuperscript{10}, David Hildick-Smith\textsuperscript{11}, Patrizia Presbitero\textsuperscript{12}, Stephan Windecker\textsuperscript{13}, Massimo Napolano\textsuperscript{14}, Alfredo G. Cerillo\textsuperscript{15}, Mohamed Abdel-Wahab\textsuperscript{16}, Didier Tchetchet\textsuperscript{17}, Claudia Fiorina\textsuperscript{18}, Jan-Malte Sinning\textsuperscript{19}, Mauricio G. Cohen\textsuperscript{20}, Mayra E. Guerrero\textsuperscript{21}, Brian Whisenant\textsuperscript{22}, Fabian Nietlispach\textsuperscript{23}, José Honório Palma\textsuperscript{2,6}, Luis Nombela-Franco\textsuperscript{24}, Arend de Weger\textsuperscript{25}, Malek Kass\textsuperscript{26}, Fabio Sandoli de Brito Jr.\textsuperscript{27}, Pedro A. Lemos\textsuperscript{2,27}, Ran Kornowski\textsuperscript{28}, John Webb\textsuperscript{3}, and Danny Dvir\textsuperscript{3,29*}
Figure 2 Incidence of coronary obstruction following valve-in-valve procedures according to surgical bioprosthesis type.

VIVID registry. EHJ 2017 (in press)
Figure 3: Distribution of distance between a virtual transcatheter ring at a size of the implanted device at the level of the coronary artery (VTC) in controls and in patients suffering coronary obstruction of the left coronary artery (LCA) and right coronary artery (RCA). The optimal cut-off level of 4 mm best predicts this complication for left coronary obstruction (AUC 0.943; P < 0.001). All cases of RCA obstruction also occurred with concomitant LCA occlusion.

VIVID registry. EHJ 2017 (in press)
**Figure 4** Kaplan–Meier survival curve at 1-year follow-up of patients undergoing transcatheter aortic valve implantation for degenerated bioprosthetic valve (valve-in-valve) with coronary obstruction.

VIVID registry. EHJ 2017 (in press)
Mortality prediction after transcatheter treatment of failed bioprosthetic aortic valves utilizing various international scoring systems: Insights from the Valve-in-Valve International Data Registry (VIVID)
Stentless vs. Stented Aortic Valve-in-Valve Implantation: Insights from the Valve-in-Valve International Data Registry (VIVID)
Aortic VinV in Stentless Surgical Valves

<table>
<thead>
<tr>
<th>Valve Type</th>
<th>Stented</th>
<th>Mosaic</th>
<th>Stentless</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>THV Malposition - Stented vs. Mosaic vs. Stentless</td>
<td>12%</td>
<td>14%</td>
<td>15%</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Second Prosthesis Needed - Stented vs. Stentless</td>
<td>4%</td>
<td>7%</td>
<td>6%</td>
<td>p = 0.004</td>
</tr>
<tr>
<td>Coronary Obstruction - Stented vs. Stentless</td>
<td>1%</td>
<td>2%</td>
<td>3%</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

Final Mean Gradient (mean ± SD)

<table>
<thead>
<tr>
<th>Valve Type</th>
<th>Stented</th>
<th>Stentless</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>17.2 ± 9.2</td>
<td>11.7 ± 7</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
</tbody>
</table>
Incidence, predictors and clinical outcomes of residual stenosis after aortic valve-in-valve

Survival - Severe PPM of the Transcatheter Heart Valve

Survival (%)

p-value = 0.81

Time (Months)

91%
Clinical outcomes of male vs. female patients undergoing transcatheter aortic valve-in-valve implantation
Clinical outcomes

<table>
<thead>
<tr>
<th></th>
<th>Male</th>
<th>Female</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>30 Days Death</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male (n = 950)</td>
<td>38 (4.2%)</td>
<td>41 (6.2%)</td>
<td>0.07</td>
</tr>
<tr>
<td>Female (n = 696)</td>
<td>41 (6.2%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>30 Days Cardiovascular Death</strong></td>
<td>32 (3.7%)</td>
<td>37 (5.9%)</td>
<td>0.04</td>
</tr>
</tbody>
</table>
Lotus Aortic ViV
ViV using the Lotus Device

• 33 cases using the Lotus mechanically-expanding valve were identified
  • Age 75.1 ± 11.8 years
  • 72.7% males
  • STS PROM 4.4 ± 3.1%

• Surgical valve characteristics
  • Label size was 24.4 ± 1.6 mm
  • Stented bioprosthesis: n = 26, 78.8%
  • Mechanism of failure: regurgitation (16 patients; 48.5%), stenosis (6 patients; 18.2%) and mixed failure (11 patients; 33.3%)
ViV using the Lotus Device

- Transfemoral access used in 96.8% of cases, with 72.7% under local anaesthesia/conscious sedation
- Pre-dilation in 6.5% of cases, with none requiring post-dilation
- Retrieval and repositioning in 15.6% of cases
  - Satisfactory end positioning in all cases
- No coronary obstruction cases
- No worse than mild aortic regurgitation
  - Mild AR: 11.1%
No 30-days death!

- Major stroke: 3.7%
- Major bleeding: 3.7%
- Major vascular complication: 6.5%
- Minor vascular complications: 9.7%
- New PPM: 4.3%
Clinical valve thrombosis after transcatheter valve-in-valve implantation for degenerated bioprosthetic aortic valves
Incidence of valve thrombosis after VIV

VIV-TAVI, N=294

Antiplatelets
n = 196

Valve thrombosis, N=22

Oral Anticoagulants
n = 98

Valve thrombosis, N=1

Incidence of valve thrombosis on antiplatelets = 11.2%
ECHO findings

Mean aortic valve gradient

At TAVR: 14.1 ± 7.5 mmHg
At Diagnosis: 35.9 ± 14.3 mmHg

p < 0.001
Treatment and outcomes

• Oral anticoagulants (phenprocoumon/NOACs)
  • Mean aortic gradients reduced significantly.
  • There were no deaths directly related to valve thrombosis.
Incidence of valve thrombosis after VIV-TAVI, N=297

Mosaic/Hancock Surgical Valve
n = 101
Valve thrombosis, N=13 (12.9%)

Other Surgical Valves
n = 196
Valve thrombosis, N=10 (5.1%)
P = 0.01

Incidence of valve thrombosis after Mosaic/Hancock VIV = 12.9%

Incidence of valve thrombosis after Mosaic/Hancock VIV and antiplatelet therapy = 20.7%
(1 out of every 5 patients)
Valve-in-Valve Transcatheter Aortic Implantation in Degenerative Sutureless Bioprostheses

Landes U¹, Dvir D², Schoels W³, Tron C⁴, Ensminger S⁵, Simonato M⁶, Schäfer U⁷, Bunc M⁷, Aldea G⁸, Cerillo A⁹, Windecker S¹⁰, Marzocchi A¹¹, Webb J², Kornowski R¹
Transcatheter Tricuspid Valve-in-Valve Implantation for the Treatment of Dysfunctional Surgical Bioprosthetic Valves
An International, Multicenter Registry Study

Doff B. McElhinney, MD; Allison K. Cabalka, MD; Jamil A. Aboulhosn, MD; Andreas Eicken, MD; Younes Boudjemline, MD; Stephan Schubert, MD; Dominique Himbert, MD; Jeremy D. Asnes, MD; Stefano Salizzoni, MD; Martin L. Bocks, MD; John P. Cheatham, MD; Tarek S. Momenah, MD; Dennis W. Kim, MD; Dietmar Schranz, MD; Jeffery Meadows, MD; John D.R. Thomson, MD; Bryan H. Goldstein, MD; Ivory Crittendon III, MD; Thomas E. Fagan, MD; John G. Webb, MD; Eric Horlick, MD; Jeffrey W. Delaney, MD; Thomas K. Jones, MD; Shabana Shahanavaz, MD; Carolina Moretti, MD; Michael R. Hainstock, MD; Damien P. Kenny, MD; Felix Berger, MD; Charanjit S. Rihal, MD; Danny Dvir, MD; for the Valve-in-Valve International Database (VIVID) Registry
Tricuspid VinV
Survival free from TVIV reintervention

Transcatheter Valve-in-Ring Implantation for the Treatment of Residual or Recurrent Tricuspid Valve Dysfunction After Prior Surgical Repair

Jamil Aboulhosn, MD, Allison K. Cabalka, MD, Daniel S. Levi, MD, Dominique Himbert, MD, Luca Testa, MD, Azeem Latib, MD, Raj R. Makkar, MD, Younes Boudjemline, MD, Dennis W. Kim, MD, Joelle Kefer, MD, Sabine Bleiziffer, MD, Gunter Kerst, MD, Danny Dvir, MD, Doff B. McElhinney, MD
Tricuspid annuloplasty data specifying type of annuloplasty ring and presence and degree of paravalvular leak (PVL) following transcatheter tricuspid valve-in-ring (TVIR) implantation. The numbers in parenthesis indicate the number of patients for the given type of ring and grade of PVL. CE MC3 = Carpentier-Edwards MC 3.
Transcatheter Tricuspid Valve-in-Valve Implantation in Patients with Ebstein Anomaly: Analysis of Medium-Term Outcomes
TVIV N=81

- TS/TR N=9
  - N=2
  - Dysfunction N=7
  - Reintervention N=8
  - Alive No Reintervention No Dysfunction N=62
- Thrombosis N=4
  - N=3
  - Dysfunktion
- Endocarditis N=4
  - N=2
- Patient-Prosthesis Mismatch N=1

Death N=4
Intermediate-Term Valve-Related Outcomes After Transcatheter Tricuspid Valve-in-Valve or Valve-in-Ring Replacement
OPTIMAL REDO Trial
Prospective Randomized Controlled Trial
All risk groups of operable patients with failed aortic bioprostheses meeting study inclusion/exclusion criteria (n=450)

2:1 Randomization

Transcatheter VIV (n=300)  Surgical Redo (n=150)

Primary Endpoint: A composite of all-cause mortality, major non-fatal stroke and redo surgery at 1 year (superiority)