ΒΑΛΒΙΔΑ ΣΤΗ ΒΑΛΒΙΔΑ (VIV)
ΔΙΑΚΑΘΕΤΗΡΙΑΚΗ ΠΡΟΣΕΓΓΙΣΗ
Η ΕΛΛΗΝΙΚΗ ΕΜΠΕΙΡΙΑ

Χριστόφορος Σ. Κωτούλας
Καρδιοχειρουργός
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ΣΥΓΚΡΟΥΣΗ ΣΥΜΦΕΡΟΝΤΩΝ: ΟΧΙ
National Registry Data and Record Linkage to Inform Postmarket Surveillance of Prosthetic Aortic Valve Models Over 15 Years

Graeme L. Hickey, PhD; Ben Bridgewater, PhD, FRCS, (C-Th); Stuart W. Grant, MB, ChB, PhD; John Deanfield, MB, BChir, FRCP; John Parkinson, PhD; Alan J. Bryan, MD, FRCS, (C-Th); Malcolm Dalrymple-Hay, PhD, FRCS, (C-Th); Neil Moat, FRCS; Iain Buchan, MD, FFPH; Joel Dunning, PhD, FRCS, (C-Th)

![Graph showing the number of valves over financial years: Biological valve type declining, Mechanical valve type increasing.](chart.png)

**Number of valves**
- Black: 1000
- Orange: 2000
- Maroon: 3000
- Deep maroon: 4000
- Light maroon: 5000

**Valve type**
- Orange: Biological
- Blue: Mechanical
ΔΙΑΚΑΘΕΤΗΡΙΑΚΕΣ ΤΕΧΝΙΚΕΣ

• Αύξηση των βιοπροθέσεων
• Αύξηση του προσδόκιμου ζωής των ασθενών
• REDO επεμβάσεις υψηλού ρίσκου
• Ανάπτυξη των διακαθετηριακών τεχνικών

• A-VIV: TA – TF
• M-VIV: TA
• M-VIR: TA
• P-VIV: TF
• T-VIV: TF
• T-VIR: TF
VIV Β’ΗΜΑΤΑ

• Ταυτοποίηση βαλβίδας
• Ακτινολογική απεικόνιση της SHV
• Μέτρηση βαλβίδας – μέγεθος
  • Μέτρηση της αληθούς εσωτερικής διαμέτρου
• Επιλογή THV, και μέγεθος (↑1-2 mm)
• Εμφύτευση
  • Οδός προσπέλασης
  • Αναγνώριση του κινδύνου απόφραξης στεφανιαίων αγγείων (<2%)
ΕΙΔΙΚΕΣ ΕΠΙΣΗΜΑΝΣΕΙΣ

• ΣΤΕΝΩΣΗ
  • Μικρές προθέσεις
  • Μτχ κλίση πίεσης
  • Υπερβαλβιδική θέση ΤΗΝ

• ΑΝΕΠΑΡΚΕΙΑ
  • Επέμβαση DAVID
  • Αορτικός διαχωρισμός με τοποθέτηση μοσχεύματος
  • Άλλες επεμβάσεις
ΙΔΑΝΙΚΗ ΑΠΕΙΚΟΝΙΣΗ

• ECG-gated CT Scan
• Υπερηχοκαρδιογράφημα
ΑΠΕΙΚΟΝΙΣΗ
Figure 2 Types of aortic bioprosthesis and effect of leaflet mounting on stent ID. (A) Porcine leaflets mounted inside the stent frame (reduction in stent ID is by 2 mm); (B) pericardial leaflets mounted inside the stent frame (reduction in stent ID is by 1 mm); (C) pericardial leaflets mounted outside the stent frame (no reduction in stent ID i.e., the stent ID = true ID).
Clinical History
CABG; SAVR; Stented bioprosthesis ID: 20.0 mm;
Kidneys nephrostomy catheter (R+L);

MEDTRONIC ANALYSIS

Max Ascending Aorta Diameter (mm) 29.7
Sinotubular Junction Diameter (mm)   
  Min 26.9
  Max 27.1

ANNULUS

Diameter (mm)   
  Min 18.6
  Max 21.4
  Mean 20.0
Perimeter (mm)   
  Derived 62.7
  Diameter

Area 308.9 mm²

Sinus of Valsalva Diameter (mm)   
  LCC 33.2
  RCC 34.7
  NCC 33.3

Sinus of Valsalva Height (mm)   
  LCC 14.3
  RCC 22.6
  NCC 18.9

Coronary Ostia Height (mm)   
  Left 6.8
  Right 11.9

LVOT Diameter (mm)   
  Min 20.3
  Max 25.8

RIGHT

CIA Min Diameter (mm) 6.2
  x 9.9

EIA Min Diameter (mm) 6.6
  x 7.5

Femoral Min Diameter (mm) 6.5
  x 8.9

LEFT

CIA Min Diameter (mm) 6.9
  x 10.5

EIA Min Diameter (mm) 5.3
  x 7.6

Femoral Min Diameter (mm) 5.6
  x 9.0

Annular Angulation 30.7

Calcium: Mild □ Moderate ☑ Severe □

Please review images for direct aortic evaluation.
ΑΠΕΙΚΟΝΙΣΗ ΜΕΤΡΗΣΕΙΣ
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<th>TAVI Devices</th>
<th>Sutureless</th>
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<td>Accurate Neo</td>
<td>Enable</td>
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<tr>
<td>Biovalsalva Porcine Conduit</td>
<td>Labcor Porcine</td>
<td>Accurate TA</td>
<td>S3</td>
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<tr>
<td>Cryolife O'Brien</td>
<td>Magna</td>
<td>CoreValve and Evolut</td>
<td>Sapien and Sapien XT</td>
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<tr>
<td>Freedom Solo</td>
<td>Magna Ease</td>
<td>JenaValve</td>
<td>Perceval</td>
</tr>
<tr>
<td>Freestyle Root</td>
<td>Mitroflow</td>
<td>Lotus</td>
<td></td>
</tr>
<tr>
<td>Freestyle Valve</td>
<td>Mosaic</td>
<td>Portico</td>
<td></td>
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<tr>
<td>Pericarbon Freedom</td>
<td>Perimount</td>
<td></td>
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</tr>
<tr>
<td>Prima Root</td>
<td>Perimount 2700</td>
<td></td>
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</tr>
<tr>
<td>Toronto SPV Root</td>
<td>Soprano</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trifecta</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figure 5 The risk of coronary obstruction is determined by interaction between aortic root anatomy and the type of SHV. (A) Wide aortic root sinuses have a reduced risk of coronary obstruction; (B) narrow coronary sinuses have a higher risk of coronary obstruction. SHV, surgical heart valves; (C) valve-in-valve leads to outward displacement of the leaflets and stent posts, which can interfere with the coronary artery flow.
• Η απόσταση μεταξύ του πλαισίου της βαλβίδας και των κόλπων του Valsalva σε εγκάρσιο επίπεδο

• >6mm ελάχιστος κίνδυνος
• 4-6 mm οριακός κίνδυνος
• <4mm υψηλού κινδύνου

• ιδιαίτερος κίνδυνος σε μικρό αορτικό δακτύλιο
• Wire protection
Figure 11 High risk anatomy for coronary obstruction after a valve-in-valve procedure.
Figure 7 BAV during VIV to assess the risk of coronary obstruction. BAV with a size 21 balloon resulted in complete left main obstruction in a patient with Biocor valve size 25 (True ID of 21) where a 23 SAPIEN or Evolut R 26 would be used. One should not proceed with VIV in this situation. The red arrow points to the left main coronary artery and white arrow points to the right coronary artery. BAV, balloon aortic valvuloplasty; VIV, valve-in-valve.
Clinical History
SAVR; bioprosthetic ID 18.0mm

**MEDTRONIC ANALYSIS**

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<th>Measurement</th>
<th>Min</th>
<th>Max</th>
<th>Mean</th>
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<td>Max Ascending Aorta Diameter (mm)</td>
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<td>35.8</td>
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<tr>
<td>Sinotubular Junction Diameter (mm)</td>
<td>25.5</td>
<td>28.2</td>
<td></td>
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<tr>
<td>Diameter (mm)</td>
<td>16.1</td>
<td>20.5</td>
<td>18.3</td>
</tr>
<tr>
<td>Perimeter (mm)</td>
<td>57.0</td>
<td>18.1</td>
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<tr>
<td>Area (mm²)</td>
<td>251.3</td>
<td>17.9</td>
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**ANNULUS**

<table>
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<th>Diameter (mm)</th>
<th>LCC</th>
<th>RCC</th>
<th>NCC</th>
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<td>27.2</td>
<td>26.5</td>
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<tr>
<td>Sinus of Valsalva Height (mm)</td>
<td>18.4</td>
<td>17.0</td>
<td>14.5</td>
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<tr>
<td>Coronary Ostia Height (mm)</td>
<td>11.2</td>
<td>9.5</td>
<td></td>
</tr>
<tr>
<td>LVOT Diameter (mm)</td>
<td>19.4</td>
<td>23.9</td>
<td>21.6</td>
</tr>
</tbody>
</table>

**Calculation**

- Calcium: Moderate

*Please review images for direct aortic evaluation.*
ΘΕΣΗ ΤΗΣ ΒΑΛΒΙΔΑΣ
ΥΠΟΛΟΓΙΣΜΟΣ ΥΨΟΥΣ ΣΤΕΦΑΝΙΑΙΩΝ ΑΓΓΕΙΩΝ
ΞΕΝΟΜΟΣΧΕΥΜΑ

- Υπολογισμός μεγέθους με CT SCAN
- Μπορεί να μην υπάρχει ασβέστωση
- Ασβεστοποιημένο μόσχευμα
- Επίπεδο της βαλβίδας
Figure 4 Neo-annulus of a SHV as a reference plane for THV deployment. (A) The neo-annulus corresponds to the sewing ring of a surgical valve e.g., the Carpentier Edwards porcine valve, where the waist of the balloon matches the sewing ring marker; (B) ideal deployment is 3–4 mm below the neo-annulus. SHV, surgical heart valves; THV, transcatheter heart valves.
Figure 6 Deployment view for a VIV procedure is critical. Align the SHV so as to align the neo-annulus in one plane. Examples of different SHVs: (A) CE porcine valve; (B) Mitroflow; (C) Soprano. VIV, valve-in-valve; SHV, surgical heart valves.
EVOLUT R 23 IN MAGNA EASE 19
EVOLUT R 26 IN BIOCORE 24

LIMA –LAD
PTCA LMS - Cx
EVOLUT R 26 IN BIOCORE 24
ΛΑΘΟΣ ΘΕΣΗ

Εμπειρία
Ακατάλληλο-λάθος μέγεθος
SHV ακτινολογική απεικόνιση
Figure 9 Examples of malposition. (A) Deep placement of a CoreValve within a Mitroflow SHV; (B) deep placement of a SAPIEN within a Hancock II SHV.
ΧΑΡΑΚΤΗΡΙΣΤΙΚΑ ΤΗΝ

• **EVOLUT R**  μικρότερη κλίση πίεσης
• **SAPIEN**  Μιτροειδής – Τριγλώχινα – Πνευμονική
• **LOTUS**  Αστήρικτες βαλβίδες
  Μικρότερος κίνδυνος απόφραξης στεφανιαίων
• **MELODY**  Πνευμονική
RUSSIAN DOLL EVENT

- Αορτική ρίζα <21mm
- BVF
- BASILICA
Bioprosthetic Valve Fracture to Facilitate Transcatheter Valve-in-Valve Implantation

Keith B. Allen, MD, Adnan K. Chhatriwalla, MD, David J. Cohen, MD, MS, John T. Saxon, MD, Sanjeev Aggarwal, MD, Anthony Hart, MD, Suzanne Baron, MD, MS, J. Russell Davis, MD, Alex F. Pak, MD, Danny Dvir, MD, and A. Michael Borkon, MD

Saint Luke’s Mid America Heart Institute and University of Missouri-Kansas City, Kansas City, Missouri; and St. Paul’s Hospital, Vancouver, British Columbia, Canada

Background. Valve-in-valve transcatheter aortic valve replacement is less effective in small surgical bioprostheses. We evaluated the feasibility of bioprosthetic valve fracture with a high-pressure balloon to facilitate valve-in-valve transcatheter aortic valve replacement.

Methods. In vitro bench testing on aortic tissue valves was performed on 19-mm and 21-mm Mitroflow (Sorin, Milan, Italy), Magna and Magna Ease (Edwards Lifesciences, Irvine, CA), Trifecta and Biocor Epic (St. Jude Medical, Minneapolis, MN), and Hancock II and Mosaic (Medtronic, Minneapolis, MN). High-pressure balloons Tru Dilation, Atlas Gold, and Dorado (C.R. Bard, Murray Hill, NJ) were used to determine which valves could be fractured and at what pressure fracture occurred.

Results. Mitroflow, Magna, Magna Ease, Mosaic, and Biocor Epic surgical valves were successfully fractured using high-pressure balloon 1 mm larger than the labeled valve size whereas Trifecta and Hancock II surgical valves could not be fractured. Only the internal valve frame was fractured, and the sewing cuff was never disrupted. Manufacturer’s rated burst pressures for balloons were exceeded, with fracture pressures ranging from 8 to 24 atmospheres depending on the surgical valve. Testing further demonstrated that fracture facilitated the expansion of previously constrained, underexpanded transcatheter valves (both balloon and self-expanding) to the manufacturer’s recommended size.

Conclusions. Bench testing demonstrates that the frame of most, but not all, bioprosthetic surgical aortic valves can be fractured using high-pressure balloons. The safety of bioprosthetic valve fracture to optimize valve-in-valve transcatheter aortic valve replacement in small surgical valves requires further clinical investigation.
Fig 2. (A) Initial setup for high-pressure balloon (HPB) inflation consists of a large syringe, indeflator, and high-pressure tubing and stop cock. (B) The HPB is rapidly filled with a syringe (1) and then the stopcock (2) is turned to allow the indeflator to further pressurize the balloon to desired atmospheres. Successful valve fracture is characterized by a sudden drop in the pressure on the indeflator gauge and often accompanied by an audible snap.
<table>
<thead>
<tr>
<th>Manufacturer/Brand</th>
<th>Valve Size</th>
<th>Bard TRU Balloon Fracture/Pressure</th>
<th>Bard Atlas Gold Balloon Fracture/Pressure</th>
<th>Appearance After Fracture</th>
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<tr>
<td>St. Jude Trifecta</td>
<td>19 mm</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>21 mm</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>St. Jude Biocor Epic</td>
<td>21 mm</td>
<td>YES / 8 ATM</td>
<td>YES / 8 ATM</td>
<td></td>
</tr>
<tr>
<td>Medtronic Mosaic</td>
<td>19 mm</td>
<td>YES / 10 ATM</td>
<td>YES / 10 ATM</td>
<td></td>
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<tr>
<td></td>
<td>21 mm</td>
<td>NO</td>
<td>NO</td>
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<td>Medtronic Hancock II</td>
<td>21 mm</td>
<td>NO</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>Sorin Mitroflow</td>
<td>19 mm</td>
<td>YES / 12 ATM</td>
<td>YES / 12 ATM</td>
<td></td>
</tr>
<tr>
<td></td>
<td>21 mm</td>
<td>YES / 18 ATM</td>
<td>YES / 18 ATM</td>
<td></td>
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<tr>
<td>Edwards MagnaEase</td>
<td>19 mm</td>
<td>YES / 24 ATM</td>
<td>YES / 24 ATM</td>
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<tr>
<td></td>
<td>21 mm</td>
<td>YES / 24 ATM</td>
<td>YES / 24 ATM</td>
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</table>

1. Balloons sized 1 mm larger than valve size.
2. Medtronic Mosaic and Sorin Mitroflow have no metal in ring therefore appearance after fracture unchanged.

Fig 3. Summary of bench testing of high pressure balloon inflation to fracture the valve frame of commercial US surgical tissue valves. (ATM = atmospheres; TRU = Tru Dilation.)
Ex vivo fluoroscopic images of fractured Magna (A) and Magna Ease (B) bioprosthetic valves.


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Fig 4. A fractured 21-mm Mitroflow (Sorin, Milan, Italy). The Dacron sewing cuff has been partially removed, demonstrating the clean fracture site in the plastic sewing ring (X). Note that the radiopaque cloth strip (white arrow) remains intact after valve fracture and prevents fluoroscopy from documenting valve fracture (insert).
Fig 5. Fully expanded 23-mm Evolut R (Medtronic Inc, Minneapolis, MN) with manufacturer’s measurements (A). After deployment of a 23-mm Evolut R in an intact 21-mm Magna (Edwards Lifesciences, Irving, CA), the transcatheter valve is constrained, as viewed from (B) below and (C) above, with mildly distorted leaflets and (D) only expands to 19 mm, which is the true internal diameter of surgical valve. After deployment of the 23-mm Evolut R valve in a fractured 21-mm Magna valve, the leaflet coaptation, as viewed from (E) above and (F) below, appears normal and (G) the transcatheter valve appears optimally deployed at 22.9.
Fig 6. (A) Fully expanded 23-mm Sapien XT (Edwards Lifesciences, Irving, CA) with manufacturer’s measurements. (B) After deployment of the 23-mm Sapien XT in an intact 21-mm Magna (Edwards Lifesciences), the transcatheter valve is constrained and only expands to 19.1 mm. (C) After deployment of the 23-mm Sapien XT in a fractured 21-mm Magna surgical valve using only the device delivery balloon, the transcatheter valve remained slightly underdeployed at 22.3 mm. (D) Optimal expansion to 23-mm was only accomplished after postdilating the valve using a 24-mm noncompliant balloon with high pressure inflation.
Fig 7. Computed tomography without contrast of the chest 1-month after VIV TAVR with surgical valve fracture demonstrates a fully expanded transcatheter valve within the fractured valve ring.
Computed tomography (CT) reconstruction of a patient who underwent valve-in-valve (VIV) transcatheter aortic valve replacement (TAVR) with a 23-mm CoreValve Evolut R in a 19-mm Edwards Magna, followed by bioprosthetic valve fracture (BVF).

• Περιπτώσεις μικρού αορτικού δακτυλίου
• Περιπτώσεις υψηλού υπολειπομένου gradient
• Γενικώς ασφαλής μέθοδος
• Ερωτήματα
  • Προ-ΤΑVI ή μετά-ΤΑVI
  • Σε περίπτωση μετά, τότε τι επίδραση στη ΤΗV
• Στάνταρντ τακτική σε όλες τις περιπτώσεις;
BASILICA SYSTEM
ΤΕΧΝΟΛΟΓΙΚΗ ΕΞΕΛΙΞΗ SHV
INSPIRIS
RESILIA Aortic Valve
An ideal foundation for your patient's future

VFit technology
VFit technology incorporates two novel features designed for potential future valve-in-valve (ViV) procedures:

- Fluoroscopically visible size markers
- Expansion zone
THE CROWNING TOUCH: EXPERIENCE DESIGNS PERFORMANCE

CROWN PRT is the latest advancement in stented aortic bioprosthesis technology, featuring surgeon-friendly design, optimal hemodynamics and the patented Phospholipid Reduction Treatment (PRT) to bolster durability through mitigation of calcium uptake.
MITRAL VIV

- EDWARDS SAPIEN FAMILY
- Διακορυφαία – δια του μεσοκολπικού διαφράγματος
- Τοποθέτηση μεγαλύτερου μεγέθους βαλβίδας
  - Εμβολή
  - LVOTO
TRANSCATHETER MVR

Braile Biomedica
Braile Biomedica
CardiAQ 1st G
CardiAQ Edwards
Cephea
Direct Flow Medical
Twelve Medtronic
M-Valve
Edwards Fortis
HighLife
Navigate
Neovasc Tiara
PermaValve MID
Sinomed
Tendyne Abbott
SATURN TMVR
Valtech CardioValve
Caisson

Others: MitraHeal, Mitrassist, Mitraltech, Mehr Medical, Mitracath, Mitralix MAESTRO, Nakostech, St. George ATLAS, Transcatheter Technologies Tresillo
Η ΕΛΛΗΝΙΚΗ ΕΜΠΕΙΡΙΑ
ΝΟΣΟΚΟΜΕΙΑ

• ΥΓΕΙΑ  13 – 6
• ΑΓΙΟΣ ΛΟΥΚΑΣ  9
• ΩΚΚ  8
• ΙΠΠΟΚΡΑΤΕΙΟ  4
• ΠΑΝΕΠΙΣΤΗΜΙΟ ΙΩΑΝΝΙΝΩΝ  2
• 401 ΓΣΝΑ/ΕΡΡΙΚΟΣ ΝΤΥΝΑΝ ΗΣ  2
• ΣΥΝΟΛΟ  38 – 6
ΓΕΝΙΚΑ ΣΤΟΙΧΕΙΑ

- ΠΕΡΙΟΔΟΣ: 2013-2017
- ΆΝΔΡΕΣ: ΓΥΝΑΙΚΕΣ: 25:19
- ΗΛΙΚΙΑ: 75,15 (61-90)
- EUROSCORE: 31.41 (17-49,9)
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<td>&gt;10 ΕΤΗ</td>
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ΝΟΣΗΛΕΙΑ

• ΜΕΣΗ ΝΟΣΗΛΕΙΑ 7,2 Η (5-13)
• ΠΡΟΣΠΕΛΑΣΗ
  • ΔΙΑΜΗΡΙΑΙΑ
  • ΔΙΑ ΤΗΣ ΥΠΟΚΛΕΙΔΙΟΥ
  • ΔΙΑΟΡΤΙΚΗ
  • ΔΙΑΚΟΡΥΦΑΙΑ
• ΘΝΗΤΟΤΗΤΑ 2 (4,54%)
SHV
19MM – 27MM

- SORIN FREEDOM
- PERIMOUNT
- MEDTRONIC
- SJM TRIFECTA
- SJM
- HOMOGRAFT
- BIOCORE
- MITROFLOW
- MOSAIC
- MAGNA EASE
THV
23MM – 34MM

- MEDTRONIC COREVALVE
- EDWARDS FAMILY
- PORTICO SJM
MITRAL VIV/VIR

- M – VIV 3
- M – VIR 3
- PERIMOUNT 27MM 3
- COSGROVE RING 2
- PHYSIO RING 1
- EDWARDS SAPIEN 3
- EDWARDS XT 3
Valvular Heart Disease

Transcatheter Aortic Valve Replacement for Degenerative Bioprosthetic Surgical Valves

Results From the Global Valve-in-Valve Registry

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Background—Transcatheter aortic valve-in-valve implantation is an emerging therapeutic alternative for patients with a failed surgical bioprosthesis and may obviate the need for reoperation. We evaluated the clinical results of this technique using a large, worldwide registry.

Methods and Results—The Global Valve-in-Valve Registry included 202 patients with degenerated bioprosthetic valves (aged 77.7±10.4 years; 52.5% men) from 38 cardiac centers. Bioprosthesis mode of failure was stenosis (n=85; 42%), regurgitation (n=68; 34%), or combined stenosis and regurgitation (n=49; 24%). Implanted devices included CoreValve (n=124) and Edwards SAPIEN (n=78). Procedural success was achieved in 93.1% of cases. Adverse procedural outcomes included initial device malposition in 15.3% of cases and ostial coronary obstruction in 3.5%. After the procedure, valve maximum/mean gradients were 28.4±14.1/15.9±8.6 mm Hg, and 95% of patients had ≤+1 degree of aortic regurgitation. At 30-day follow-up, all-cause mortality was 8.4%, and 84.1% of patients were at New York Heart Association functional class I/II. One-year follow-up was obtained in 87 patients, with 85.8% survival of treated patients.

Conclusions—The valve-in-valve procedure is clinically effective in the vast majority of patients with degenerated bioprosthetic valves. Safety and efficacy concerns include device malposition, ostial coronary obstruction, and high gradients after the procedure. (Circulation. 2012;126:2335-2344.)

Key Words: bioprosthesis ■ transcatheter aortic valve implantation ■ valve-in-valve
The Global Valve-in-Valve Registry
Kaplan–Meier survival curve of patients undergoing transcatheter aortic valve replacement for degenerated bioprosthetic valve (valve-in-valve).

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Safety and Efficacy of Transcatheter Aortic Valve Replacement in the Treatment of Pure Aortic Regurgitation in Native Valves and Failing Surgical Bioprostheses

Results From an International Registry Study

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ABSTRACT

OBJECTIVES The aim of this study was to evaluate the use of transcatheter heart valves (THV) for the treatment of noncalcific pure native aortic valve regurgitation (NAVr) and failing bioprosthetic surgical heart valves (SHVs) with pure severe aortic regurgitation (AR).

BACKGROUND Limited data are available about the “off-label” use of transcatheter aortic valve replacement (TAVR) to treat pure severe AR.

METHODS The study population consisted of patients with pure severe AR treated by TAVR at 18 different centers. Study endpoints were device success, early safety, and clinical efficacy at 30 days, as defined by Valve Academic Research Consortium 2 criteria.

RESULTS A total of 145 patients were included, 78 patients in the NAVr group and 68 patients in the failing SHV group. In the NAVr group, device success, early safety, and clinical efficacy were 72%, 66%, and 6%, respectively. Device success and clinical efficacy were significantly better with newer-generation THVs compared with older-generation THVs (85% vs. 54% and 75% vs. 46%, respectively, p < 0.05), this was mainly due to less second THV implantations and a lower rate of moderate to severe paravalvular regurgitation (10% vs. 24% and 3% vs. 27%, respectively). Independent predictors of 30-day mortality were body mass index < 20 kg/m², STS surgical risk score > 8%, major vascular or access complication, and moderate to severe AR. In the failing SHV group, device success, early safety, and clinical efficacy were 71%, 90%, and 77%, respectively.

CONCLUSIONS TAVR for pure NAVr remains a challenging condition, with older-generation THVs being associated with THV embolization and migration and significant paravalvular regurgitation. Newer generation THVs show more promising outcomes. For these patients with severe AR due to failing SHVs, TAVR is a valuable therapeutic option.
Transcatheter aortic valve implantation in failed bioprosthetic surgical valves.


Abstract

IMPORTANCE: Owing to a considerable shift toward bioprosthesis implantation rather than mechanical valves, it is expected that patients will increasingly present with degenerated bioprostheses in the next few years. Transcatheter aortic valve-in-valve implantation is a less invasive approach for patients with structural valve deterioration; however, a comprehensive evaluation of survival after the procedure has not yet been performed.

OBJECTIVE: To determine the survival of patients after transcatheter valve-in-valve implantation inside failed surgical bioprosthetic valves.

DESIGN, SETTING, AND PARTICIPANTS: Correlates for survival were evaluated using a multinational valve-in-valve registry that included 459 patients with degenerated bioprosthetic valves undergoing valve-in-valve implantation between 2007 and May 2013 in 55 centers (mean age, 77.6 [SD, 9.8] years; 56% men; median Society of Thoracic Surgeons mortality prediction score, 9.8% [interquartile range, 7.7%-16.6%]). Surgical valves were classified as small (≤21 mm; 29.7%), intermediate (>21 and ≤25 mm; 39.3%), and large (≥25 mm; 31%). Implanted devices included both balloon- and self-expandable valves.

MAIN OUTCOMES AND MEASURES: Survival, stroke, and New York Heart Association functional class.

RESULTS: Modes of bioprosthesis failure were stenosis (n = 181 [39.4%]), regurgitation (n = 139 [30.3%]), and combined (n = 139 [30.3%]). The stenosis group had a higher percentage of small valves (37% vs 20.9% and 26.6% in the regurgitation and combined groups, respectively; P = .005). Within 1 month following valve-in-valve implantation, 35 (7.6%) patients died, 8 (1.7%) had major stroke, and 313 (92.6%) of surviving patients had good functional status (New York Heart Association class I/II). The overall 1-year Kaplan-Meier survival rate was 83.2% (95% CI, 80.8%-84.7%; 62 death events; 228 survivors). Patients in the stenosis group had worse 1-year survival (76.6%; 95% CI, 68.9%-83.1%; 34 deaths; 86 survivors) in comparison with the regurgitation group (91.2%; 95% CI, 85.7%-96.7%; 10 deaths; 76 survivors) and the combined group (83.9%; 95% CI, 76.8%-91%; 18 deaths; 66 survivors) (P = .01). Similarly, patients with small valves had worse 1-year survival (74.8% [95% CI, 66.2%-83.4%]; 27 deaths; 57 survivors) vs with intermediate-sized valves (81.8% [95% CI, 75.3%-88.3%]; 26 deaths; 92 survivors) and with large valves (93.3% [95% CI, 85.7%-96.7%; 7 deaths; 73 survivors) (P = .001). Factors associated with mortality within 1 year included having small surgical bioprosthesis (≤21 mm; hazard ratio, 2.04; 95% CI, 1.14-3.67; P = .02) and baseline stenosis (vs regurgitation; hazard ratio, 3.07; 95% CI, 1.33-7.08; P = .008).

CONCLUSIONS AND RELEVANCE: In this registry of patients who underwent transcatheter valve-in-valve implantation for degenerated bioprosthetic aortic valves, overall 1-year survival was 83.2%. Survival was lower among patients with small bioprostheses and those with predominant surgical valve stenosis.
Table 5: Intermediate Clinical Outcomes in Matched Cohort (median follow-up 1.3 years)

<table>
<thead>
<tr>
<th></th>
<th>Redo SAVR (n=32)</th>
<th>TAV-in-SAV (n=32)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke</td>
<td>1 (3%)</td>
<td>0 (0%)</td>
<td>.313</td>
</tr>
<tr>
<td>Pacemaker</td>
<td>6 (19%)</td>
<td>2 (6%)</td>
<td>.131</td>
</tr>
<tr>
<td>Wound Infection</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>-</td>
</tr>
<tr>
<td>Endocarditis</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>-</td>
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</tbody>
</table>
**Conclusions**

Compared with ReSAVR, patients who underwent ViV-TAVR had no significant difference in early mortality, but demonstrated lower in-hospital morbidity and improved resource utilization. However, ViV-TAVR was associated with higher mean gradients on postoperative echocardiography.

ViV-TAVR is a viable less invasive alternative to ReSAVR in appropriate patients with a degenerated aortic bioprosthesis. However, larger, longer-term, and prospective studies are needed to validate these single-institution findings.
ΣΥΜΠΕΡΑΣΜΑΤΑ

• Ασφαλής και Εφικτή επέμβαση
• Αποφυγή του κινδύνου επανεπέμβασης
• Σε Στένωση και Ανεπάρκεια προσθετικής βαλβίδας
• Μικρότερος χρόνος χειρουργείου
• Γρηγορότερη ανάρρωση
• Ελαχιστοποίηση μεταγγίσεων
• Τεχνολογική εξέλιξη
• Σημαντικός ρόλος και πιθανή αλλαγή στην καθημερινή πρακτική
ΕΥΧΑΡΙΣΤΩ ΠΟΛΥ ΓΙΑ ΤΗΝ ΠΡΟΣΟΧΗ ΣΑΣ

"It's worse than a piece of surgical equipment. We accidentally left the surgeon inside you."

"They wanted to meet you. This is the family of 'Mongo,' the pig who donated the valve to you."