Bioprosthetic Valve Fracture to Facilitate Valve in Valve TAVR

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Disclosures

• Proctor: Medtronic Inc

• Speaker Bureau: Edwards Lifesciences, Medtronic Inc, Abbott Vascular
Mortality After VIV TAVR

The smaller the surgical valve, the higher the mortality!

Dvir, et al. AMA. 2014; 312(2):162-170
VIV TAVR case

- Patient with severe bioprosthetic AS
- 21 mm Magna (true ID 19 mm)
- Treated with 23 mm CoreValve Evolut

Mean gradient: 36 mmHg
Aortic valve area: 0.8 cm²

Mean gradient: 26 mmHg
Aortic valve area: 1.2 cm²
Bioprosthetic Valve Fracture
Final Hemodynamics

Mean gradient: 9 mmHg

Aortic valve area: 1.6 cm²
BVF Clinical Series

• 20 patients undergoing VIV TAVR (9 centers)
  – self-expanding n=12
  – balloon-expandable n=8
• 19 transfemoral, 1 transcarotid access
• Mean: STS 8.4%
• Mean age of prosthesis: 9.5 y
• Mean true ID of valve: 17.8 mm
• TAVR performed prior to BVF in 15/20 cases

https://doi.org/10.1161/CIRCINTERVENTIONS.117.005216
Mean Gradient

Baseline: 42 ± 11 mmHg
Post-TAVR: 21 ± 7 mmHg
Post-BVF: 7 ± 4 mmHg

P < 0.001

Effective Orifice Area (AVA)

Baseline  
0.6 ± 0.2

Post-TAVR  
P<0.001  
1.0 ± 0.4

Final  
P<0.001  
1.8 ± 0.6

* Measurements only available for pts treated with BVF after ViV TAVR

https://doi.org/10.1161/CIRCINTERVENTIONS.117.005216
High-pressure balloon fracturing of small dysfunctional Mitroflow bioprostheses facilitates transcatheter aortic valve-in-valve implantation

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Complications of BVF

- 75 clinical cases (21 centers)
- Observed
  - 2 embolic stroke
  - 1 flail anterior MV leaflet — treated with mitraclip
  - 2 severe AI from TAVR valve (1 Sapien, 1 CoreValve) — treated with second device
- Theoretical
  - Aortic root or annulus rupture/injury
  - Coronary occlusion
  - Conduction abnormalities
  - Embolic debris
How Valves Fracture
CT reconstruction

23 mm CoreValve in a 21 mm Magna

Single Fracture Point  Ring Otherwise Intact
First, check to see if the surgical valve can be fractured.
Here’s what you’ll need...

- 1 Non-compliant balloon
- 1 60 cc luer lock syringe filled with dilute contrast
- 1 PTCA indeflator
- 1 high-pressure stopcock

*Disclaimer: This is 100% off-label use and requires exceeding balloon RBP considerably*
And here’s the set-up...

1. Hand Inflation

2. "Hand Inflation"

3. "Hand Inflation"

4. "Hand Inflation"
Caveat: Balloon Position

• Care must be taken not to disrupt the CoreValve “waist”
• It appears safe to use a balloon up to 2mm larger than the waist
• Ideally the proximal shoulder of the balloon should be distal to the waist of the valve
VIV TAVR in small surgical bioprostheses may be associated with increased incidence of PPM and higher mortality

Most bioprosthetic valves can be fractured with a high pressure balloon inflation

BVF results in lower residual valve gradients and larger valve EOA after VIV TAVR
BVF: Unanswered Questions

- Does BVF improve survival after VIV TAVR?
  - Reducing PPM could result in improved survival
  - Need to collect data!
BVF: Unanswered Questions

• Does BVF result in a long-term improvement in hemodynamics after VIV TAVR?

Saxon, et al. TCT 2017
BVF: Unanswered Questions

• Is it better to do BVF before or after TAVR?

• BVF First
  – Pros: no high-pressure inflation of TAVR prosthesis
  – Cons: risk for embolization or severe AI?

• TAVR First
  – Pros: Can assess results before deciding on BVF. High pressure inflation ensures optimal expansion of TAVR prosthesis
  – Cons: Could high-pressure inflation lead to acute or subacute injury to the TAVR valve?
<table>
<thead>
<tr>
<th></th>
<th>Combined</th>
<th>BVF first</th>
<th>TAVR first</th>
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<tbody>
<tr>
<td><strong>Number of patients</strong></td>
<td>30</td>
<td>15</td>
<td>15</td>
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<tr>
<td><strong>Mean age (years)</strong></td>
<td>79.0</td>
<td>82.2</td>
<td>75.7</td>
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<td><strong>Age of BPV (years)</strong></td>
<td>10.4</td>
<td>10.9</td>
<td>9.9</td>
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<tr>
<td><strong>Mean BPV true inner diameter</strong></td>
<td>17.4</td>
<td>16.6</td>
<td>18.1</td>
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<tr>
<td><strong>Hemodynamic support (ECMO)</strong></td>
<td>10</td>
<td>10</td>
<td>0 (0)</td>
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<tr>
<td><strong>Self-expanding TAVR</strong></td>
<td>12</td>
<td>2</td>
<td>10</td>
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<tr>
<td><strong>Balloon expandable TAVR</strong></td>
<td>18</td>
<td>13</td>
<td>5</td>
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<tr>
<td><strong>Baseline mean gradient</strong></td>
<td>41</td>
<td>42</td>
<td>40</td>
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<tr>
<td><strong>Baseline EOA</strong></td>
<td>0.75</td>
<td>0.7</td>
<td>0.8</td>
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<tr>
<td><strong>Post-TAVR mean gradient</strong></td>
<td>n/a</td>
<td>n/a</td>
<td>21</td>
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<tr>
<td><strong>Post-TAVR EOA</strong></td>
<td>n/a</td>
<td>n/a</td>
<td>1.0</td>
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<tr>
<td><strong>Final mean gradient</strong></td>
<td>11</td>
<td>17</td>
<td>7</td>
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<tr>
<td><strong>Final EOA</strong></td>
<td>1.7</td>
<td>1.3</td>
<td>2.0</td>
</tr>
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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.
BVF: Unanswered Questions

- Does BVF impact the durability of the TAVR prosthesis?
  - BVF might allow for optimal expansion of the TAVR prosthesis and this could improve durability of results
  - Need to collect data!
BVF: Unanswered Questions

- Could BVF be beneficial in patients with larger bioprostheses as well?
  - Even if PPM is not a concern, BVF might allow for optimal expansion of the TAVR prosthesis and this could improve durability of results
  - Need to collect data!
BVF: Unanswered Questions

• When BVF is planned, what criteria should be taken into account when selecting the TAVR prosthesis?
  – How do you decide which type and size of TAVR valve to implant?
  – Consider internal valve dimension, expected gain with BVF
  – Need to collect data!
BVF: Unanswered Questions

• What factors pre-dispose to complications with BVF?
  – Features of the aorta, sinuses, coronaries?
  – Recategorization of Virtual THV to coronary distance thresholds?
  – Need to collect data!
I thought that’s what studies were for?
VIVID Research Proposal

• Propensity Matched analysis of BVF/no-BVF

• Primary Outcomes
  – 1 year mean gradient, EOA and mortality

• Secondary Outcomes
  – Complications: AI, aortic injury, thromboembolism, coronary occlusion

• Sample size?

• Subgroup analyses based on timing of BVF and THV type
Thank You