Bioprosthetic Valve Fracture for Optimizing Results of Valve-in-Valve TAVR

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Valve-in-Valve TAVR

➢ VIV TAVR is an effective alternative to redo surgery in high or intermediate risk patients with failing tissue valves.

➢ However, VIV TAVR can be problematic with small surgical bioprostheses because of further reduction in the effective orifice leading to high residual gradients.
Impact of Surgical Valve Size on 1-Year Mortality

VIVID Registry

- 459 pts with failed surgical bioprostheses treated with ViV TAVR (59% balloon expandable, 41% self-expanding)
- Patients stratified based on size of original surgical valve
  - Small ≤ 21 (n=133)
  - Medium 22-24 (n=176)
  - Large ≥ 25 (n=139)
- Small surgical valve independently associated with 1-year mortality (HR 2.04, p=0.02)

Dvir D, et al. JAMA 2014;312:162-170
Patient P.M.

- 71 y.o. man with bioprosthetic valve degeneration
- Underwent AVR/CABG x 3 in 2007 (19 mm Magna)
- Did well until late 2015 when he began to notice increasing DOE and fatigue
- **Echo**: normal LV and RV size, LVEF 65%, aortic valve gradient 60 mmHg (peak 79 mmHg) with trivial AI
- Referred for redo AVR vs. TAVR → felt to be high risk due to patent grafts and proximity of RV to sternum → ViV TAVR

#19 Magna Valve: True Internal Diameter 17 mmHg
Planned for 23 mm CoreValve EVOLUT
Baseline Hemodynamics

Mean gradient = 63 mmHg  AVA 0.8 cm²
Valve Implant (23 mm CoreValve EVOLUT)
Post-TAVR and Post-Dilation

Mean gradient = 44 mmHg  AVA 1.0 cm²
In-Lab Conversation (Paraphrased)

- **IC**: This isn’t good. We still have almost as high a gradient as when we started.

- **CTS**: I know how to treat this. We can break the surgical valve.

- **IC**: What?? Are you crazy?

- **CTS**: I heard about it at a meeting recently. A surgeon from LA said he had done it a few times.

- **IC**: Really? I still think you’re crazy. Just like when you told us that transcarotid TAVR was a good idea.
Here’s what you’ll need...

- 1 True Dilatation or ATLAS-GOLD 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...
BVF: More Photogenic Example
Post- 20 mm Tru Balloon (16 atm)

Mean gradient = 18 mmHg    AVA 1.9 cm²
And here’s how it works…

Early deterioration of Mitroflow aortic bioprostheses (Sorin Group Inc), particularly small sizes 19 and 21 mm, has been reported. Treatment of failing bioprostheses by transcatheter valve-in-valve (VIV) therapy has become an alternative to repeat surgery. However, VIV treatment is problematic with small surgical bioprostheses because of a further reduction in the effective valve orifice. One way to overcome this challenge may be to fracture the ring of the surgical valve by high-pressure balloon dilation before implanting a larger size transcatheter valve. The feasibility of this approach was recently reported for an Edwards Perimount bioprosthesis (19 mm) in the pulmonary position. We report the first cases in vitro and in man of high-pressure balloon dilatation to fracture the ring of small dysfunctional Mitroflow aortic bioprostheses followed by transcatheter VIV implantation.

The Mitroflow bioprosthesis is build from a bovine pericardial sheet sutured to the outside of an acetyl stent to form the leaflets. The sewing ring is made from 02 stainless steel heart valve in vitro in one of the fractured 21 mm Mitroflow bioprostheses.

After in vitro testing and informed consent, we performed this procedure in 2 patients with small Mitroflow bioprostheses (19 and 21 mm) and high risk to redo surgery (Table). High-pressure balloon predilatation by an ATLAS Gold balloon led to fracturing of the stent ring of the Mitroflow valves with subsequent successful VIV with an SAPBIEN XT valve 20 mm (19 mm Mitroflow) and a SAPBIEN III 23 mm valve (21 mm Mitroflow; Table). The procedures were performed in general anaesthesia guided by fluoroscopy and TEE. Rapid right ventricular pacing (180 bpm) and cardiopulmonary support (CPB 2 units; right atrium to left femoral artery) were used during the high-pressure balloon predilatation and at the time of VIV implantation. The Mitroflow valve ring fractured at a pressure of 16 atm (Mitroflow 19 mm) and 11 atm (Mitroflow 21 mm) evident by a sudden drop in inflation pressure and resolution of the waist in the balloon with expansion of the leaflets and valve ring. The new Mitroflow and HeartSage...
Final Appearance
(1 week f/u)
Valves that can and cannot be fractured

To date, the only valves that cannot be fractured are:

Trifecta (St. Jude)
Hancock II (MDT)

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.
BVF Clinical Series

• 20 consecutive patients* from 7 US centers treated with bioprosthetic valve fracture at the time of ViV TAVR (8 at MAHI)

• Mean age 76 years; mean STS-PROM 8.4%

• Valves treated: Mitroflow, Perimount, Magna/Magna-Ease, Biocor Epic/Epic-Supra, and Mosaic

• Treated with both self-expanding (n=12) and balloon expandable (n=8) TAVR valves

• 15/20 underwent BVF after TAVR valve deployed

* 30 cases in full series as of 6/11/17

Mean Gradient

Effective Orifice Area (AVA)

Aortic Valve Area (cm²)

Baseline  | Post-TAVR  | Post-BVF
--- | --- | ---
0.6 ± 0.2 | 1.0 ± 0.4 | 1.8 ± 0.6

P<0.001

Intentional Fracture of Bioprosthetic Valves

• For patients with small bioprosthetic valves who are high risk for re-do AVR, BVF may offer a “solution” to high residual gradients after ViV implantation

• Bench testing demonstrates that most surgical valves can be fractured (except Trifecta and Hancock II)

• Clinical experience to date suggests that BVF is safe

• Unresolved questions
  – *Timing of BVF (pre vs. post-TAVR) → impact on safety and long-term TAVR valve durability*
  – *Should all ViV procedures undergo BVF (even with a low gradient) to allow for better TAVR valve geometry and function*
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