Bioprosthetic Valve Fracture (BVF) to Facilitate VIV-TAVR

Keith B. Allen MD
Department of Cardiothoracic & Vascular Surgery
Saint Luke’s Mid America Heart Institute
Kansas City, MO USA
Edwards (PARTNER, S3, Speaker’s Bureau)
Medtronic (SURTAVI, Speaker’s Bureau)
Abbott (PORTICO)
Current Indications for TAVR: Just the Tip of the Iceberg

6.2% High Risk (STS > 8%)
13.9% Intermediate Risk (STS 4-8%)
79.9% Low Risk (STS < 4%)

STS database 2002-2010 (141,905 pts)
VIV TAVR is not the Same Procedure!
- VIV TAVR carries different technical and procedural concerns such as coronary occlusion.
- Currently only approved for high-risk or inoperable patients.
Durability of VIV TAVR UNKNOWN!

Transcatheter valves placed VIV are by definition constrained and not optimally expanded and the effect on durability is unknown.

Explanted 23 S3 VIV in a 21 Magna Ease after only two years.
VIV TAVR is an effective alternative to redo surgery and approved for high risk patients with failing tissue valves.

VIV TAVR, however, can be problematic with small surgical bioprostheses because of further reduction in the effective orifice leading to high residual gradients.
The smaller the surgical valve, the higher the mortality!

1-Year Mortality After Valve-in Valve TAVR

Valve-in-Valve International Data (VIVID) Registry
Dvir, et al. JAMA 2014
PARTNER ViV Study

Impact of Residual Gradient on 1-Year Mortality

HR: 2.27 [95% CI: 1.16, 4.46]
Log-Rank P-Value =0.0140

Mean Δ ≥20 mmHg: 16.7%
Mean Δ <20 mmHg: 7.7%

VIV TAVR
RESIDUAL GRADIENTS
INCREASE MORTALITY

www.tombstonebuilder.com
‘Tricks’ to Optimize Results with VIV TAVR

It is really confusing!!!

Four

No Three
Impact of Implantation Depth on Minimizing Residual Gradients During VIV TAVR

Implantation Depth: CoreValve

1-2 mm deep is the sweet spot

Implantation Depth: Sapien XT

Sweet Spot is as Shallow as Comfort Allows
Bioprosthetic Valve Fracture (BVF) to Facilitate and Optimize VIV TAVR


- Which valves can be fractured?
- What balloons work?
- What balloon pressures are required for each valve to be fractured?
- Does surgical valve fracture allow transcatheter valves to expand optimally?
TRU DILATION and ATLAS GOLD high-Pressure balloons 1 mm larger than labeled valve size were tested on 19 & 21 mm tissue valves
Bench Testing

21mm Magna fractured with 22mm TRU Balloon

US Surgical Tissue Valves that can be Fractured

Some Valves Cannot Be Fractured

- St. Jude Trifecta
- Medtronic Avalus
- Medtronic Hancock II
In an unfractured 21 mm Magna with a true ID of 19 mm, the 23mm Evolut R is constrained to 19 mm and not optimally expanded.

Following BVF, the true ID of the 21 mm Magna increases 4 mm and the 23mm Evolut R is now optimally expanded.

BVF Optimizes Expansion of Balloon Expandable Transcatheter Valves

In an unfractured 21 mm Magna with a true ID of 19 mm, the 23 mm XT is constrained to 19 mm and not optimally expanded.

Following BVF, the true ID of the 21 mm Magna increases 4 mm and the 23 mm XT is now optimally expanded.
Set up for BVF

We recommend TAVR first then BVF

We typically use a balloon 1 mm larger than the labeled valve size
We recommend TAVR first then BVF

We typically use a balloon 1 mm larger then the labeled valve size
Early Clinical Experience
10 US Centers/30 patients
STS 2018, Poster #20

Mean Gradient (mmHg)

Baseline: 43 ± 8
Post ViV TAVR: 20.4 ± 8
After BVF: 8 ± 5

P<0.001

* For pts treated with BVF after ViV TAVR
Early Clinical Experience
10 US Centers/30 patients
STS 2018, Poster #20

Aortic Valve Area (cm²)

- Baseline: 0.6 ± 0.2
- Post VIV TAVR: 1.1 ± 0.7
- Post BVF: 2.0 ± 0.7

P<0.001

*A For pts treated with BVF after ViV TAVR

Typically gain 3.5-4mm in additional diameter with BVF

\[ A = \pi r^2 \]
BVF Complications
BVF Complications

- 2 minor strokes → no residual
- 1 chordal tear → moderate-severe MR treated with MitraClip
- 2 severe AI from disruption of TAVR valve → treated successfully with second valve-in-valve
- In-hospital/30-day mortality 1.5% (1/65)
- No coronary occlusion
- No annular rupture (clinical or subclinical)
- No new pacemakers
- 94% (61/65) no AI

* 65 cases in full series as of 1/2018
BVF Balloon Position Important
Severe AI related to detached leaflet from CoreValve frame may be prevented by correct balloon position

BVF balloon should not be more than 2 mm larger than CV constrained area

Balloon Expandable Valves Need to be Post Dilated with High Pressure Inflation Following BVF to Optimize Expansion

Edwards 23 mm XT Expanded Nominally

VIV TAVR in 21 Magna Prior to BVF

Following BVF

Following High Pressure Post Dilation


Saint Luke’s MID AMERICA HEART INSTITUTE
- Heavily calcified roots
- Intra rather then supra-annularly positioned surgical valves
- Chimney roots with effaced or absent sinus that don’t have room for valve expansion
- Coronary occlusion

Saint Luke’s MID AMERICA HEART INSTITUTE

19 mm Sorin Mitroflow
Inspiris Surgical Tissue Valve

Expansion zone
Inspiris Surgical Tissue Valve
Bioprosthetic Valve Fracture (BVF)

- May offer a “solution” to high residual gradients after VIV TAVR and improve short and long term outcomes
- BVF is generally safe (although not entirely risk-free)
- Many unresolved questions that require further study
  - 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 which may improve durability