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

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Asia Pacific Valves 2017- 10 mins

Disclosures

Grant Support/Drugs

- Daiichi-Sankyo - Eli Lilly
- Astra-Zeneca - Merck

Grant Support/Devices

- Edwards Lifesciences - Abbott Vascular
- Medtronic - Boston Scientific
- Biomet - CSI

Consulting/Advisory Boards

- Medtronic - Edwards Lifesciences

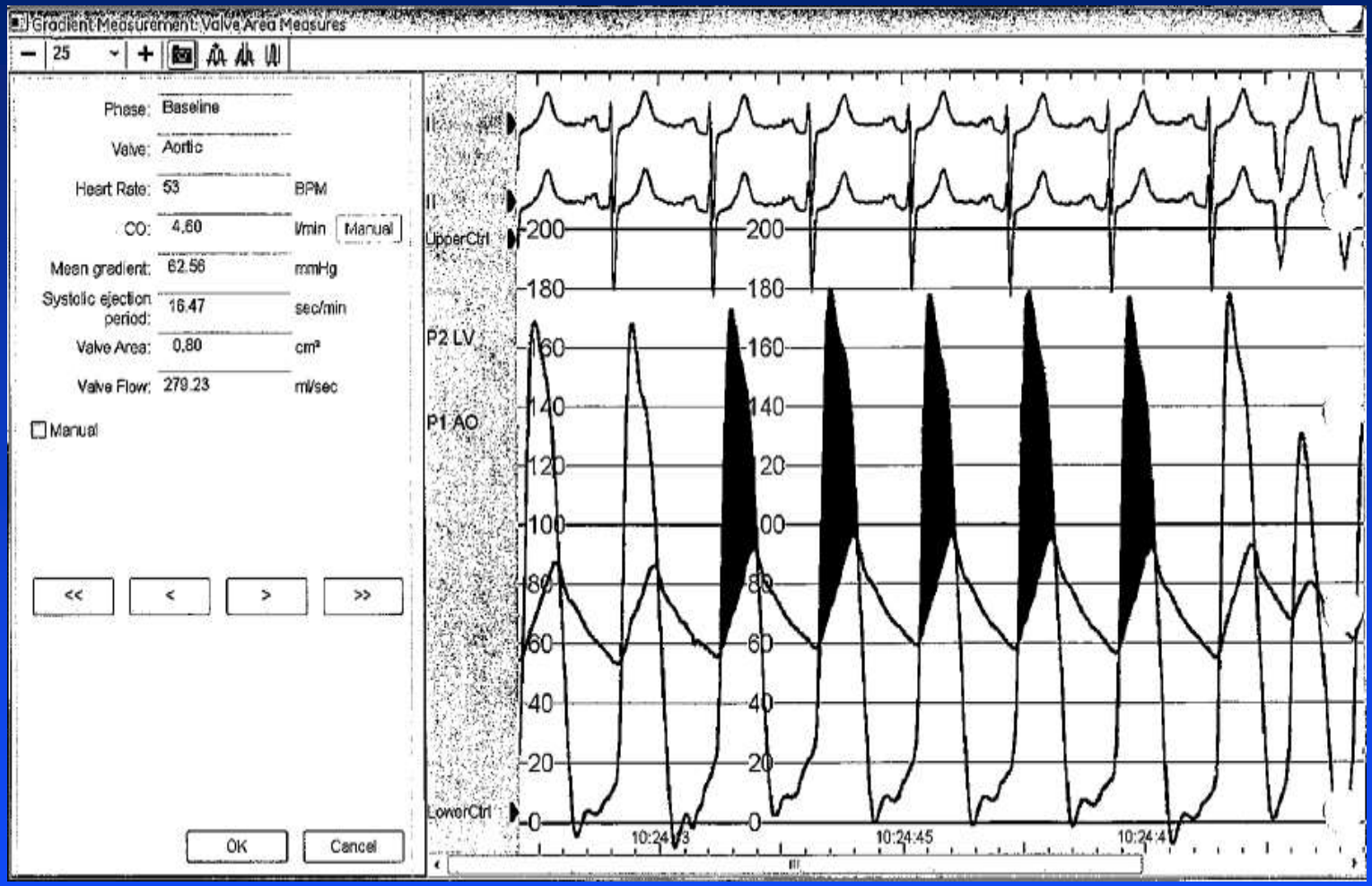
Patient P.M.

- 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

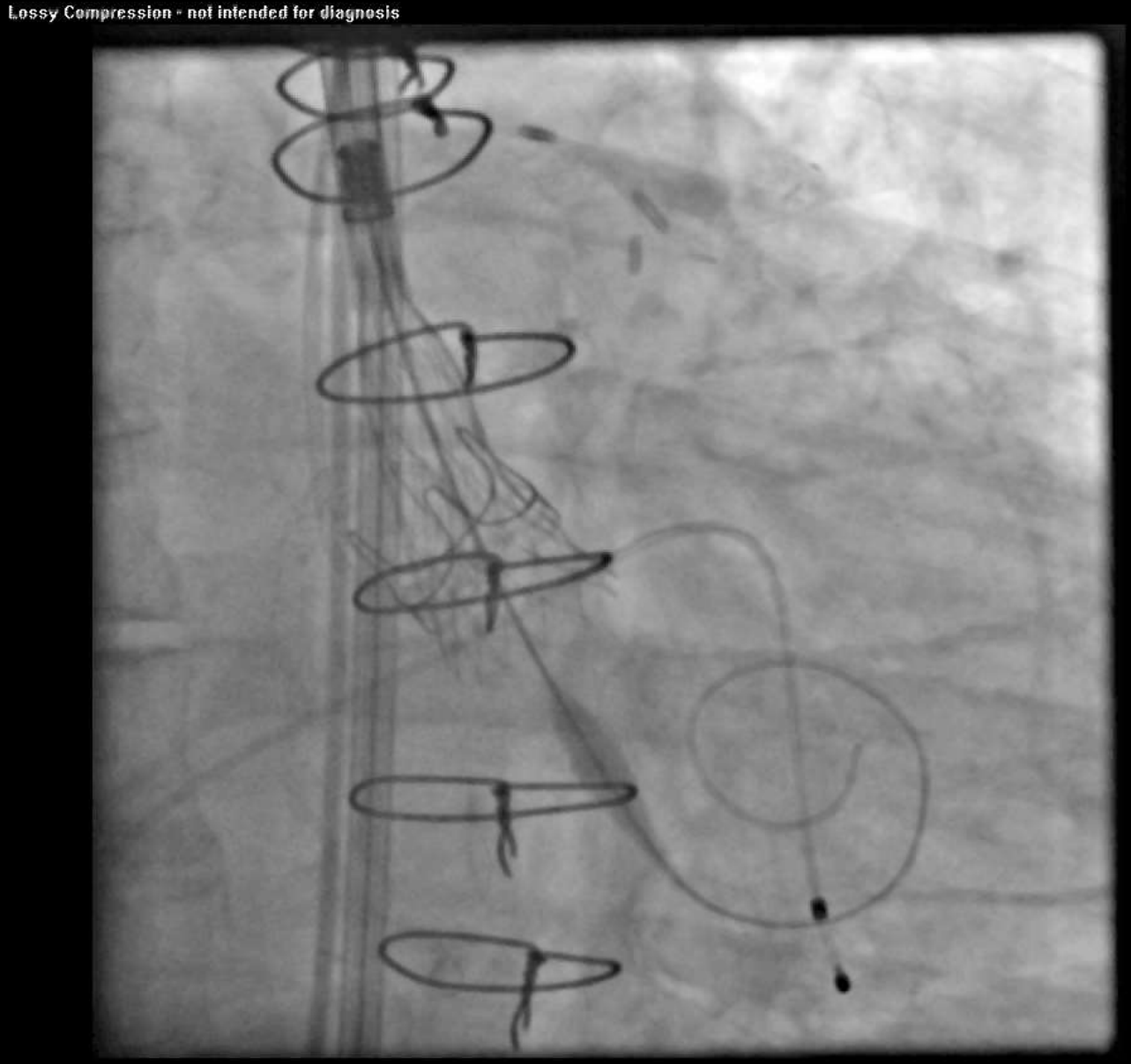
#19 Magna Valve: True Internal Diameter 17 mmHg

Planned for 23 mm CoreValve EVOLUT

Baseline Hemodynamics



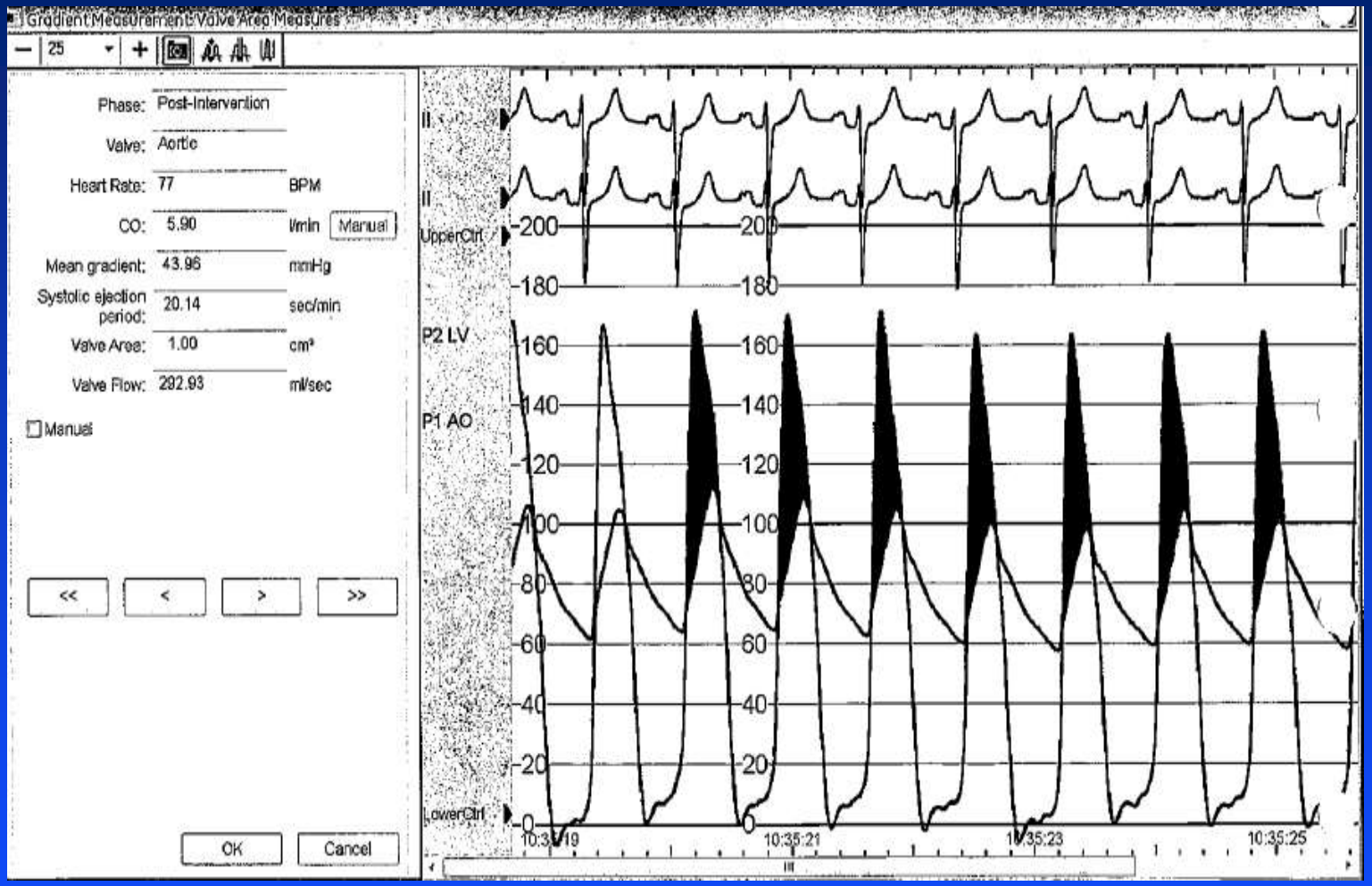
Mean gradient = 63 mmHg AVA 0.8 cm2



Valve Implant

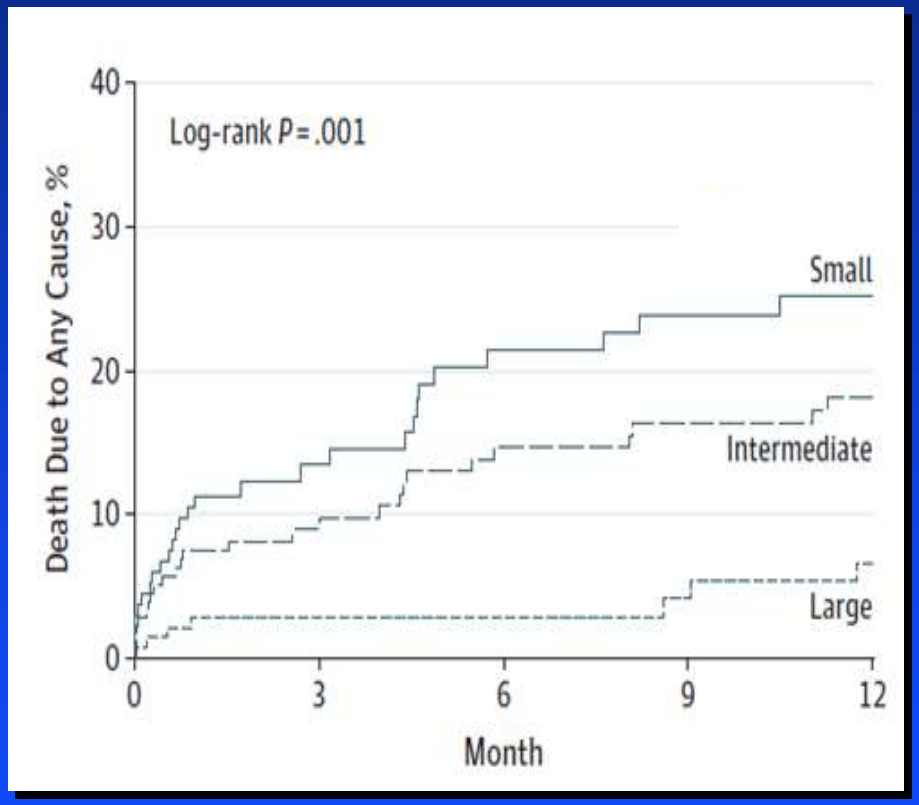
Aiming for High Implant

Post-TAVR and Post-Dilation



Mean gradient = 44 mmHg AVA 1.0 cm2

Impact of Surgical Valve Size on 1-Year Mortality

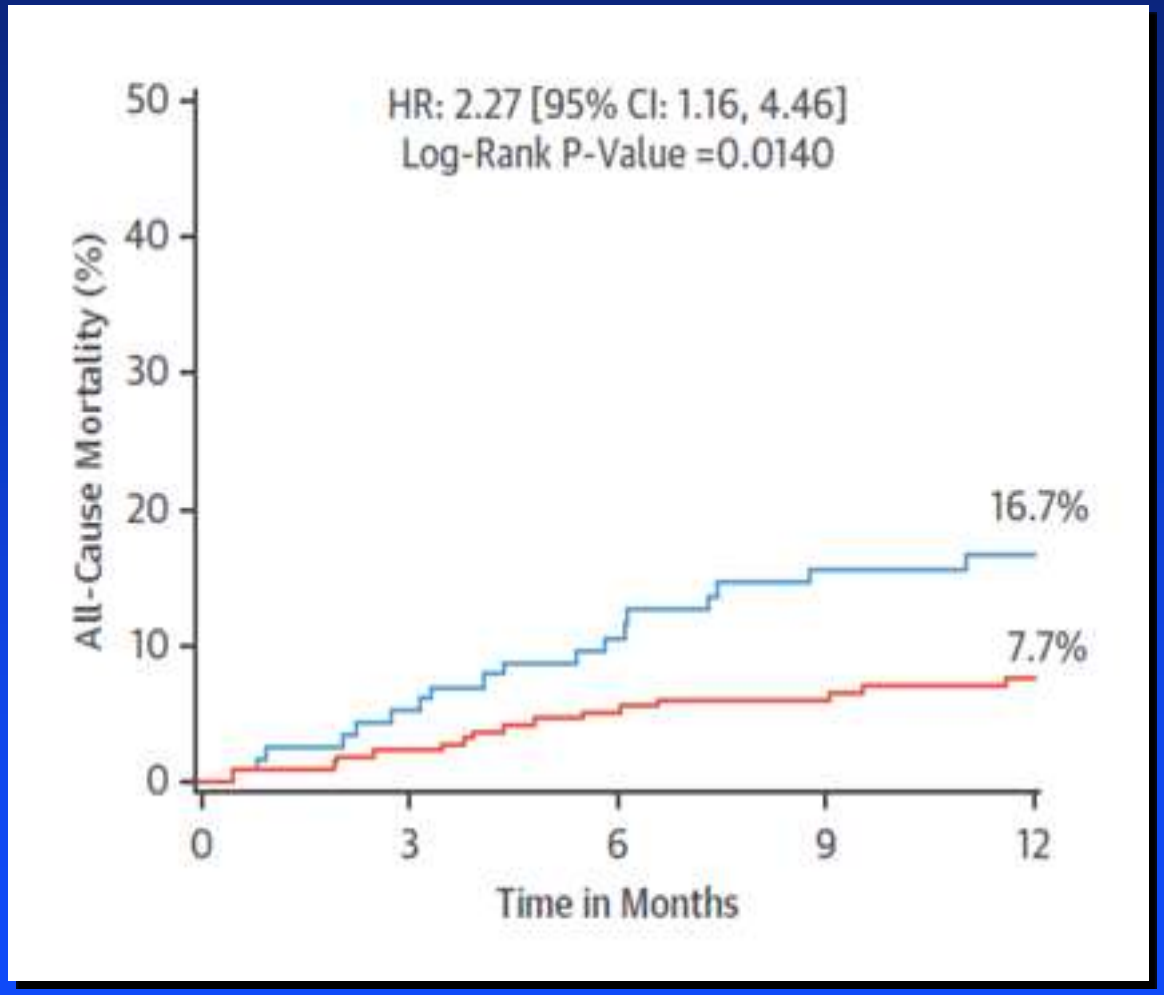


VIVID Registry

- 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

Impact of Residual Gradient on 1-Year Mortality



Mean Δ ≥20 mmHg

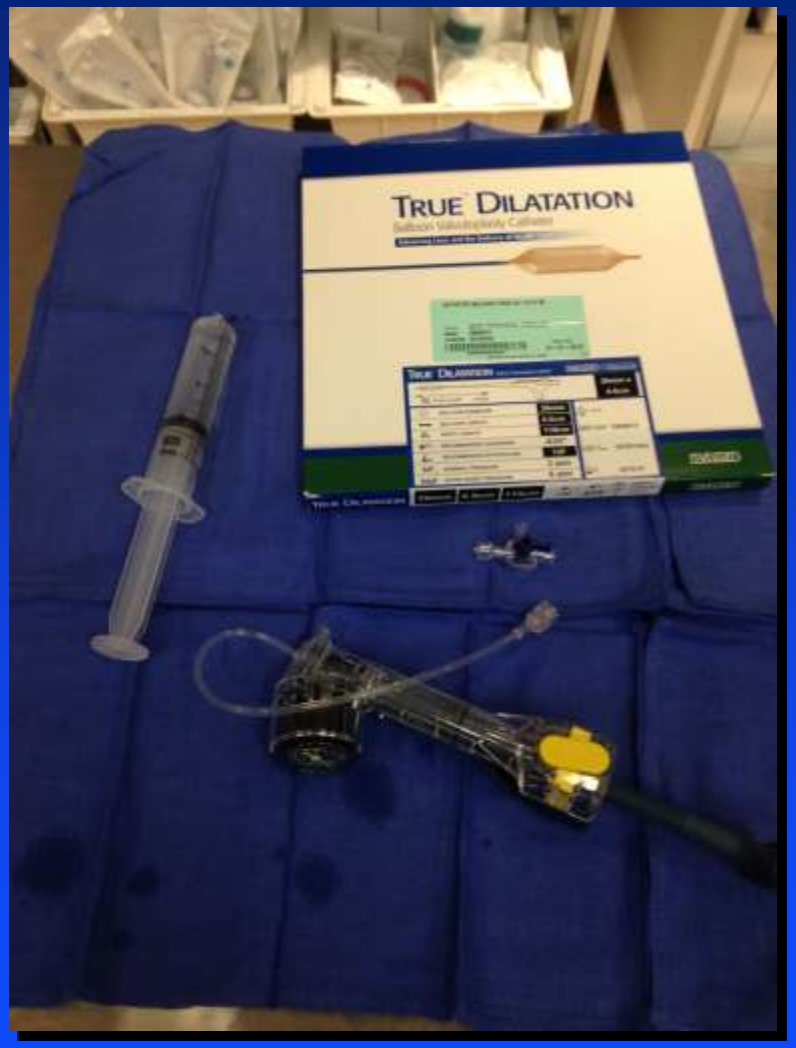
Mean Δ <20 mmHg

Webb, et al. JACC. 2017; 69:2253-62

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.

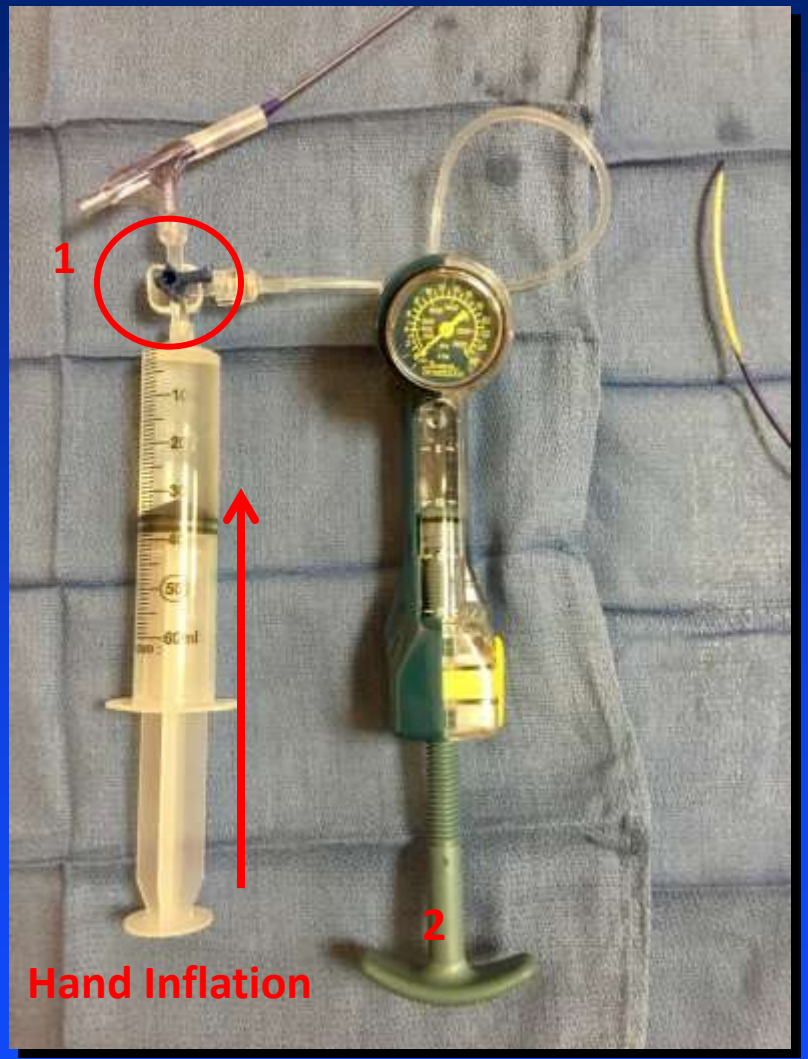
Here's what you'll need…



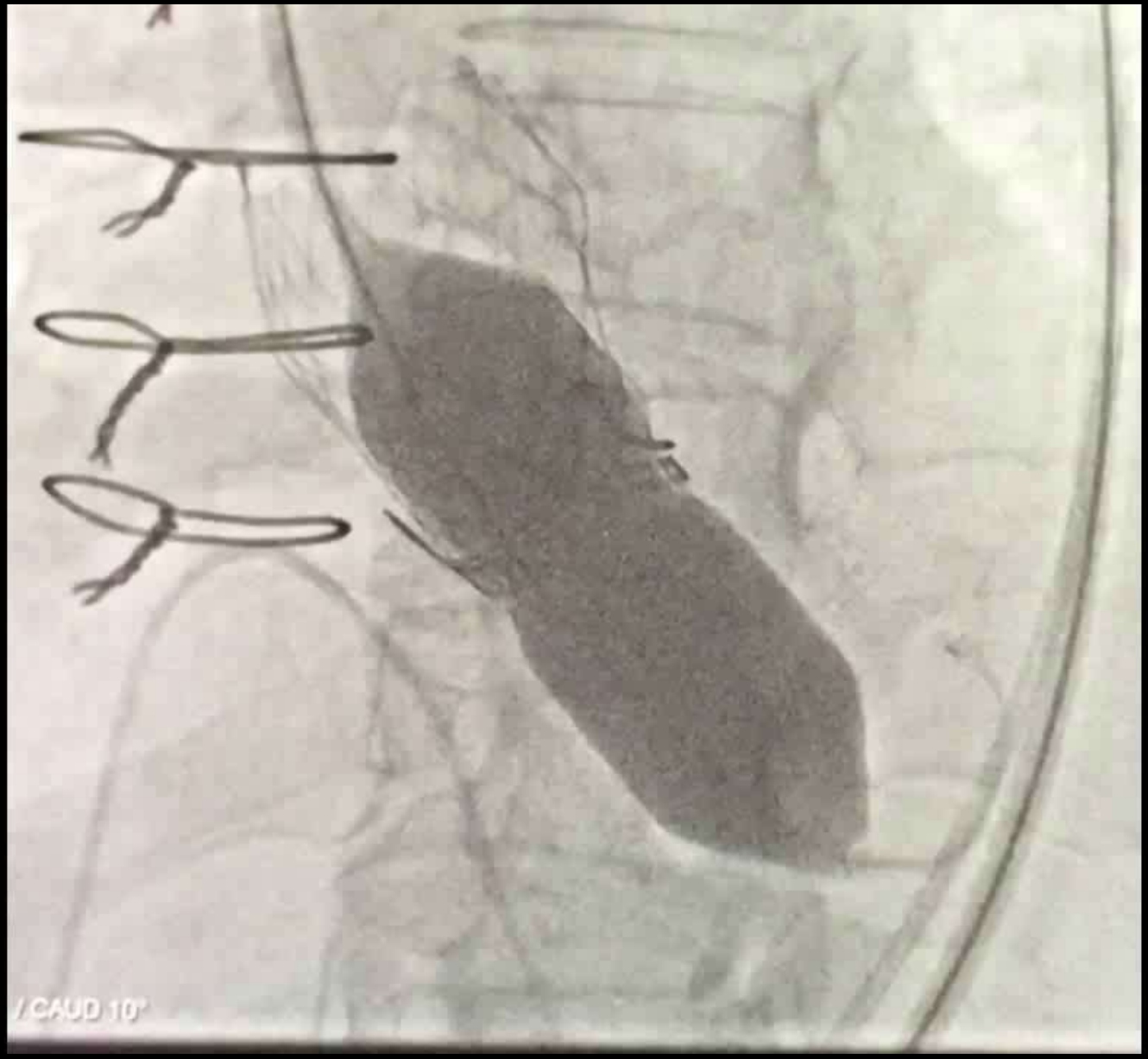
- 1 True Dilatation, ATLAS, or ATLAS-GOLD Balloon (Bard)→ Kevlar wrapped
- 1 60 cc luer lock syrine filled with dilute contrast
- 1 PTCA indeflator
- 1 high-pressure stopcock

** Disclaimer: This is 100% off-label use and may require exceeding balloon RBP considerably*

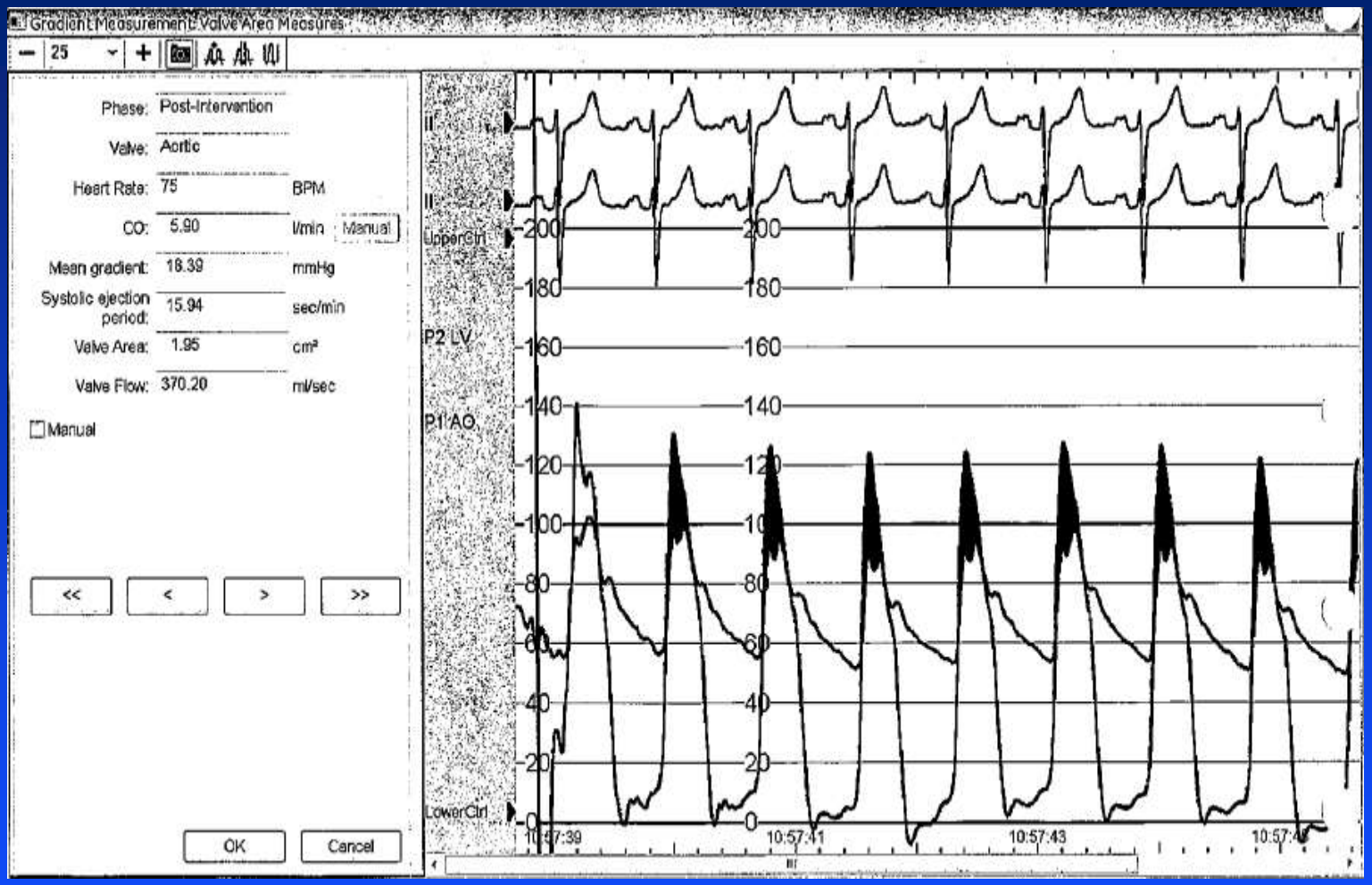
And here's the set-up…



High Pressure Post-Dilation with 20 mm True Balloon

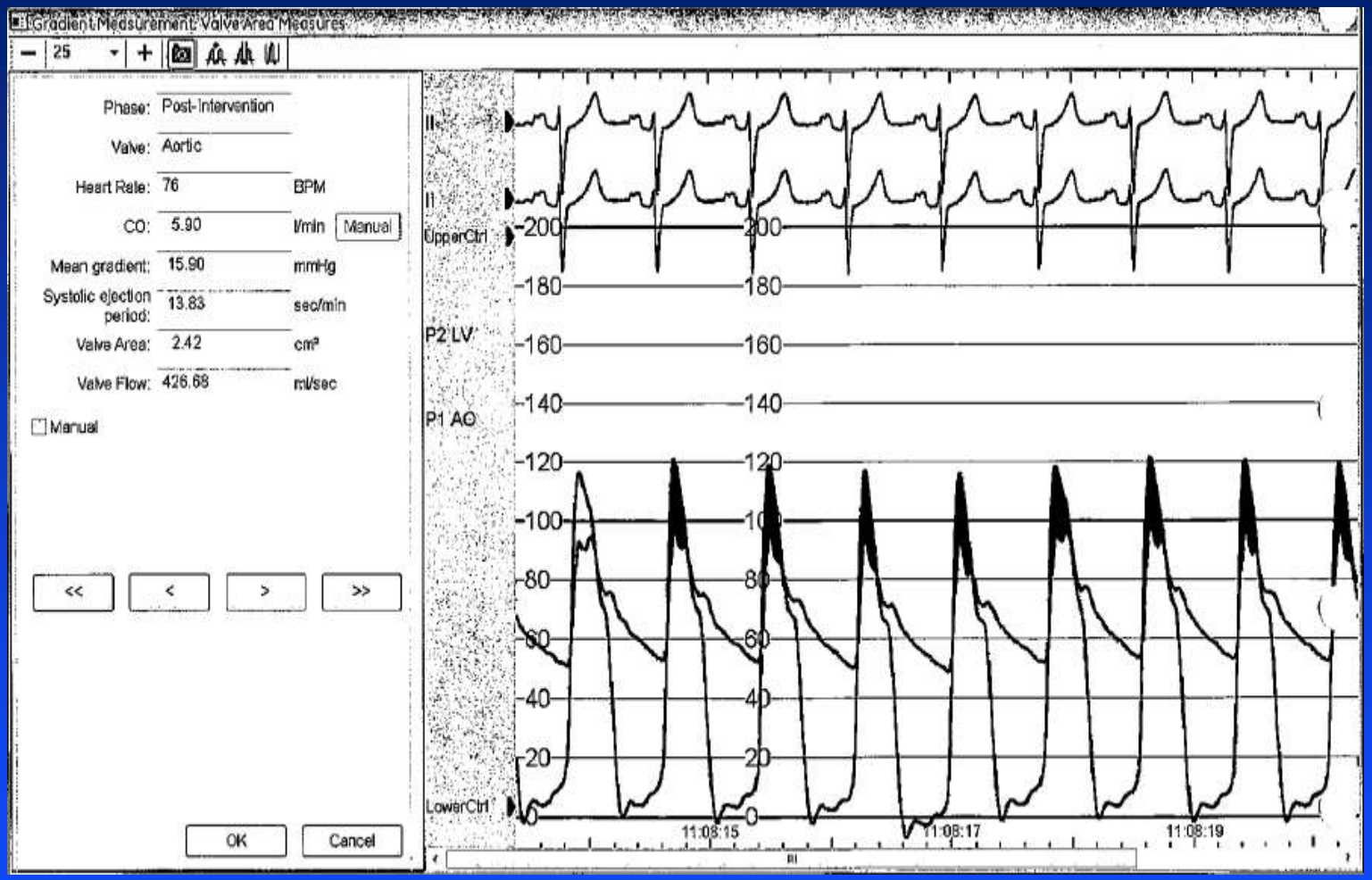


Post- 20 mm Tru Balloon (16 atm)



Mean gradient = 18 mmHg AVA 1.9 cm2

Post- 22 mm Tru Balloon (14 atm)



Mean gradient = 15 mmHg AVA 2.4 cm2

And here's how it works…

Images and Case Reports in Interventional Cardiology

Fracturing the Ring of Small Mitroflow Bioprostheses by High-Pressure Balloon Predilatation in Transcatheter Aortic Valve-in-Valve Implantation

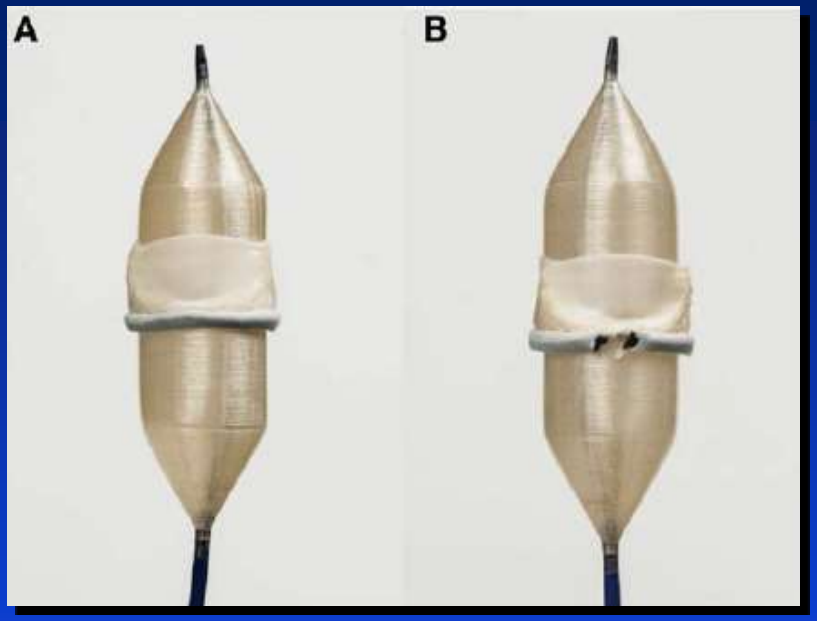
Jens Erik Nielsen-Kudsk, MD, DMSc; Evald Høj Christiansen, MD, PhD; Christian Juhl Terkelsen, MD, DMSc; Bjarne Linde Nørgaard, MD, PhD; Kaare Troels Jensen, MD, PhD; Lars Romer Krusell, MD; Mariann Tang, MD; Kim Terp, MD; Kaj-Erik Klaaborg, MD; Henning Rud Andersen, MD, DMSc

Early deterioration of Mitroflow aortic bioprostheses (Sorin Group Inc), particularly small sizes 19 and 21 mm, has been reported.[1] Treatment of failing bioprostheses by transcatheter valve-in-valve (VIV) therapy has become an alternative to repeat surgery.[2,3] 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 dilatation before implanting a larger size transcatheter valve. The feasibility of this approach was recently reported for an Edwards Perimount bioprosthesis (19 mm) in the pulmonic position.[4] 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 soft polymeric

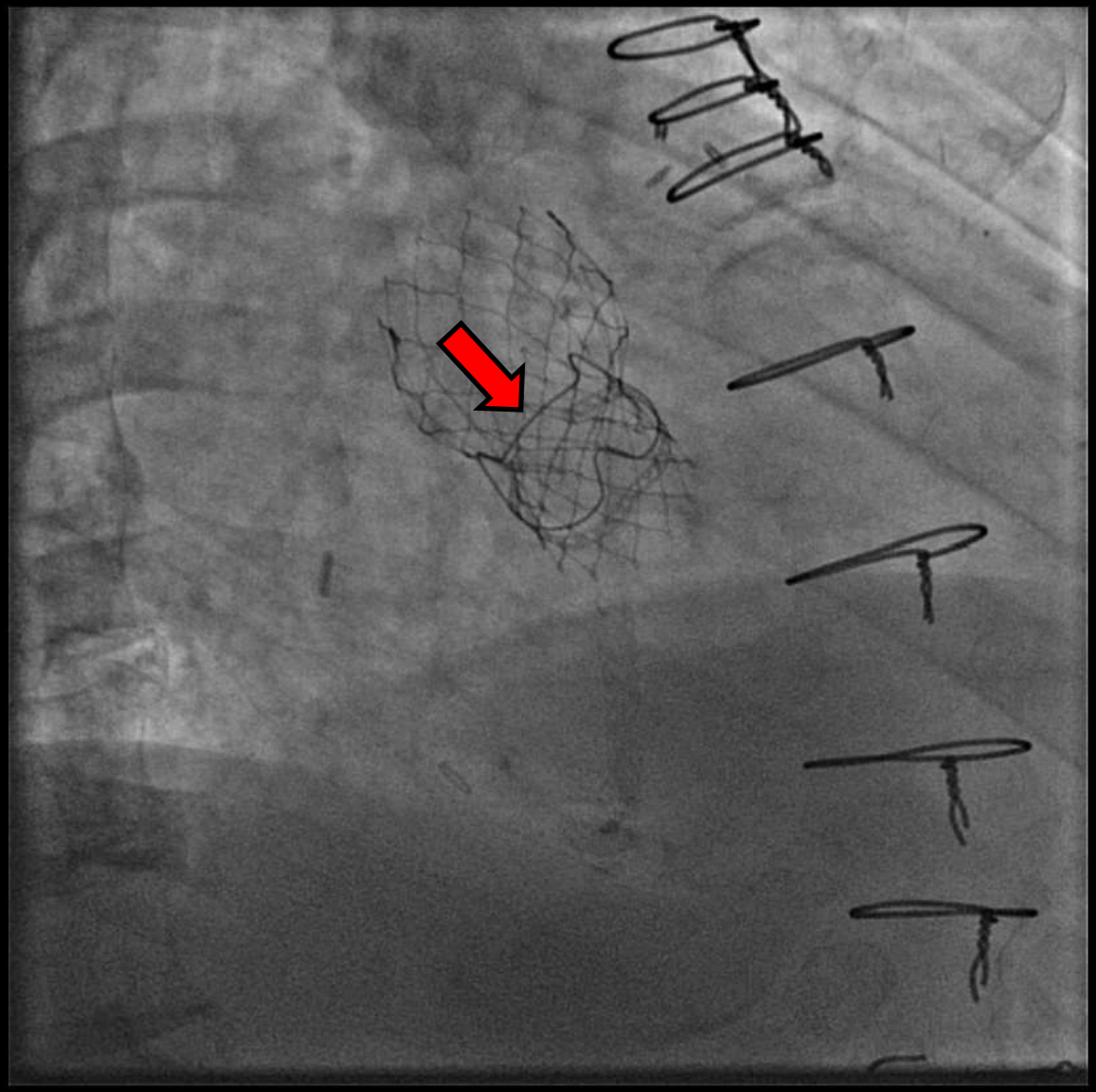
heart valve in vitro in one of the fractured 21 mm Mitroflow bioprostheses.

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 successfully VIV with an SAPIEN XT valve 20 mm (19 mm Mitroflow) and a SAPIEN III 23 mm valve (21 mm Mitroflow; Table). The procedures were performed in general anesthesia guided by fluoroscopy and TEE. Rapid right ventricular pacing (180 bpm) and cardiopulmonary support (CPS 2 l/min; 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 expan-

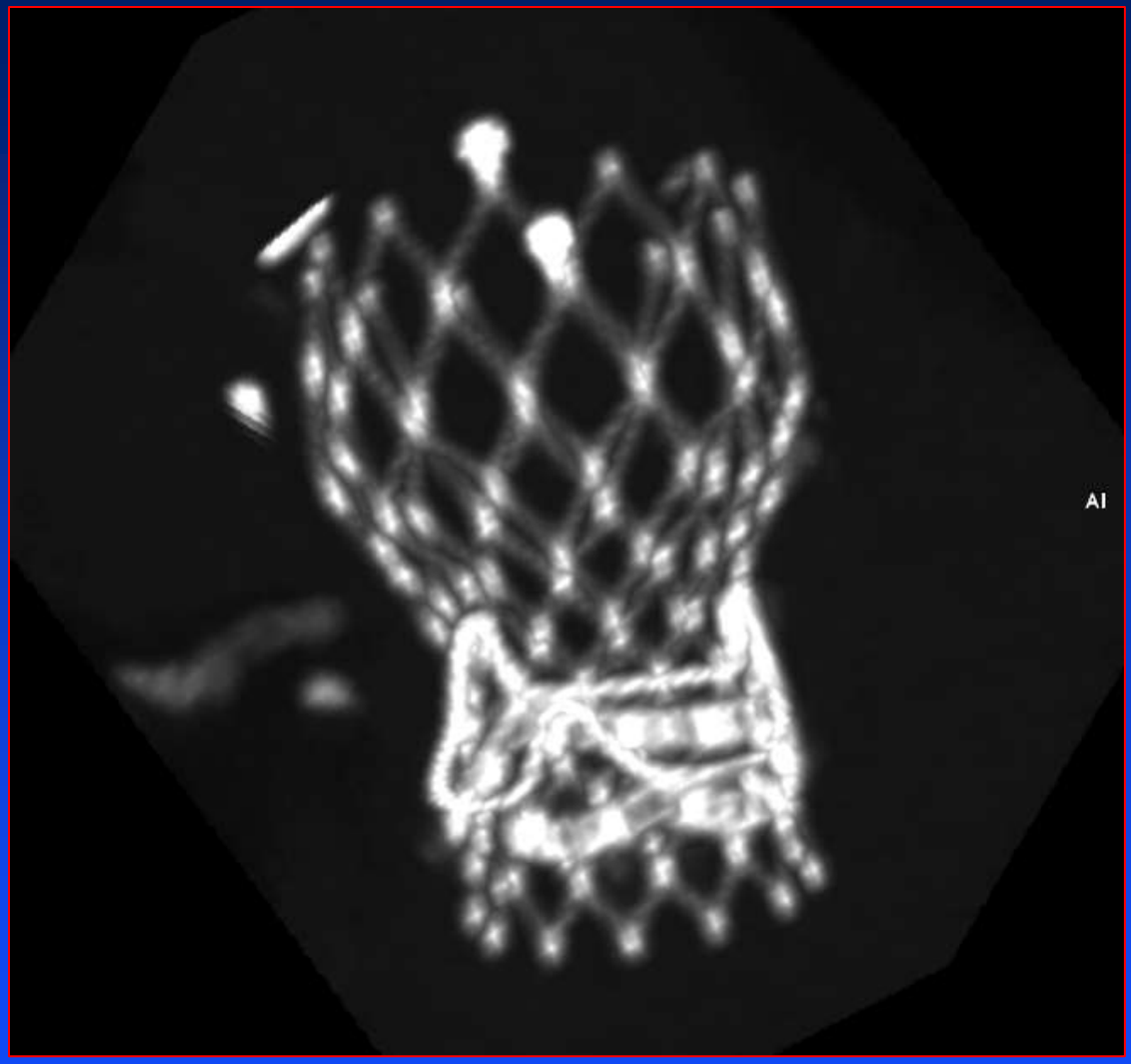


Nielsen-Kudsk JE, et al. Circ Cardiovasc Intv 2015

Final
Appearance
(1 week f/u)



CT
Reconstruction
post BVF



Systematic Bench Testing of Commercial US Surgical Tissue Valves

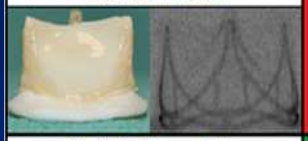
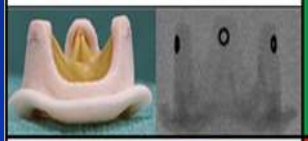
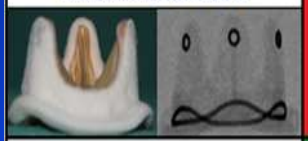
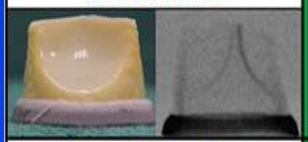
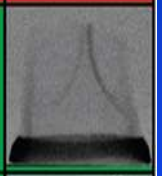
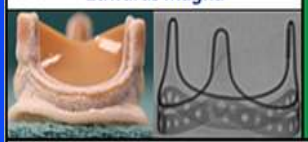
- Which valves can (and cannot) be fractured?
- Which balloons work?
- What pressures are required to fracture each type of valve?
- Does bioprosthetic valve fracture (BVF) allow transcatheter valves to expand optimally and under what conditions?

Valves that can and cannot be fractured

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

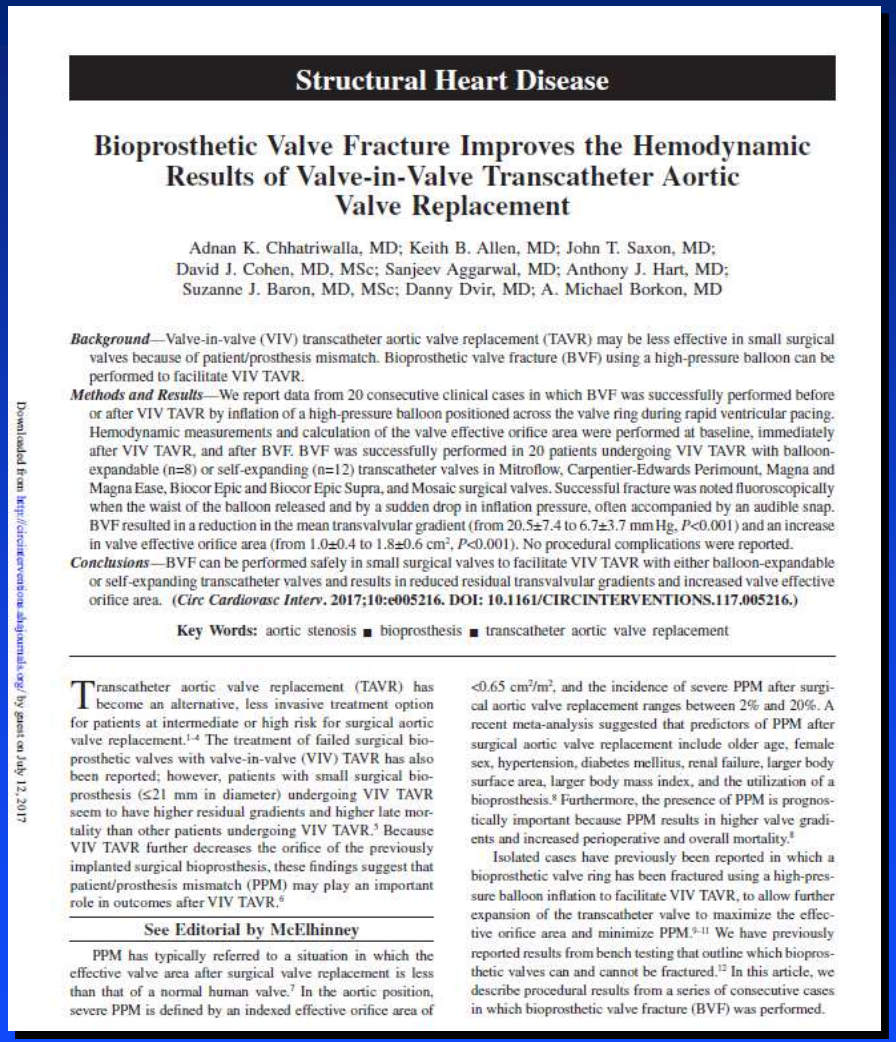
Trifecta (St. Jude)

Hancock II (MDT)

Manufacturer/ Brand	Valve Size	Bard TRU Balloon Fracture/Pressure	Bard Atlas Gold Balloon Fracture/Pressure	Appearance After Fracture
St. Jude Trifecta 	19 mm 21 mm	NO NO	NO NO	
St. Jude Biocor Epic 	21 mm	YES / 8 ATM	YES / 8 ATM	
Medtronic Mosaic 	19 mm 21 mm	YES / 10 ATM YES / 10 ATM	YES / 10 ATM YES / 10 ATM	
Medtronic Hancock II 	21 mm	NO	NO	
Sorin Mitroflow 	19 mm 21 mm	YES / 12 ATM YES / 12 ATM	YES / 12 ATM YES / 12 ATM	
Edwards MagnaEase 	19 mm 21 mm	YES / 18 ATM YES / 18 ATM	YES / 18 ATM YES / 18 ATM	
Edwards Magna 	19 mm 21 mm	YES / 24 ATM YES / 24 ATM	YES / 24 ATM YES / 24 ATM	

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



Structural Heart Disease

Bioprosthetic Valve Fracture Improves the Hemodynamic Results of Valve-in-Valve Transcatheter Aortic Valve Replacement

Adnan K. Chhatriwalla, MD; Keith B. Allen, MD; John T. Saxon, MD; David J. Cohen, MD, MSc; Sanjeev Aggarwal, MD; Anthony J. Hart, MD; Suzanne J. Baron, MD, MSc; Danny Dvir, MD; A. Michael Borkon, MD

Background—Valve-in-valve (VIV) transcatheter aortic valve replacement (TAVR) may be less effective in small surgical valves because of patient/prosthesis mismatch. Bioprosthetic valve fracture (BVF) using a high-pressure balloon can be performed to facilitate VIV TAVR.

Methods and Results—We report data from 20 consecutive clinical cases in which BVF was successfully performed before or after VIV TAVR by inflation of a high-pressure balloon positioned across the valve ring during rapid ventricular pacing. Hemodynamic measurements and calculation of the valve effective orifice area were performed at baseline, immediately after VIV TAVR, and after BVF. BVF was successfully performed in 20 patients undergoing VIV TAVR with balloon-expandable (n=8) or self-expanding (n=12) transcatheter valves in Mitroflow, Carpentier-Edwards Perimount, Magna and Magna Ease, Biocor Epic and Biocor Epic Supra, and Mosaic surgical valves. Successful fracture was noted fluoroscopically when the waist of the balloon released and by a sudden drop in inflation pressure, often accompanied by an audible snap. BVF resulted in a reduction in the mean transvalvular gradient (from 20.5±7.4 to 6.7±3.7 mm Hg, $P<0.001$) and an increase in valve effective orifice area (from 1.0±0.4 to 1.8±0.6 cm^2, $P<0.001$). No procedural complications were reported.

Conclusions—BVF can be performed safely in small surgical valves to facilitate VIV TAVR with either balloon-expandable or self-expanding transcatheter valves and results in reduced residual transvalvular gradients and increased valve effective orifice area. **(*Circ Cardiovasc Interv*. 2017;10:e005216. DOI: 10.1161/CIRCINTERVENTIONS.117.005216.)**

Key Words: aortic stenosis ■ bioprosthesis ■ transcatheter aortic valve replacement

Transcatheter aortic valve replacement (TAVR) has become an alternative, less invasive treatment option for patients at intermediate or high risk for surgical aortic valve replacement.[1-4] The treatment of failed surgical bioprosthetic valves with valve-in-valve (VIV) TAVR has also been reported; however, patients with small surgical bioprosthesis (≤21 mm in diameter) undergoing VIV TAVR seem to have higher residual gradients and higher late mortality than other patients undergoing VIV TAVR.[5] Because VIV TAVR further decreases the orifice of the previously implanted surgical bioprosthesis, these findings suggest that patient/prosthesis mismatch (PPM) may play an important role in outcomes after VIV TAVR.[6]

See Editorial by McElhinney

PPM has typically referred to a situation in which the effective valve area after surgical valve replacement is less than that of a normal human valve.[7] In the aortic position, severe PPM is defined by an indexed effective orifice area of <0.65 cm^2/m^2, and the incidence of severe PPM after surgical aortic valve replacement ranges between 2% and 20%. A recent meta-analysis suggested that predictors of PPM after surgical aortic valve replacement include older age, female sex, hypertension, diabetes mellitus, renal failure, larger body surface area, larger body mass index, and the utilization of a bioprosthesis.[8] Furthermore, the presence of PPM is prognostically important because PPM results in higher valve gradients and increased perioperative and overall mortality.[8]

Isolated cases have previously been reported in which a bioprosthetic valve ring has been fractured using a high-pressure balloon inflation to facilitate VIV TAVR, to allow further expansion of the transcatheter valve to maximize the effective orifice area and minimize PPM.[9-11] We have previously reported results from bench testing that outline which bioprosthetic valves can and cannot be fractured.[12] In this article, we describe procedural results from a series of consecutive cases in which bioprosthetic valve fracture (BVF) was performed.

- 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 <u>after</u> TAVR valve deployed

* 38 cases in full series as of 8/15/17

BVF Clinical Series

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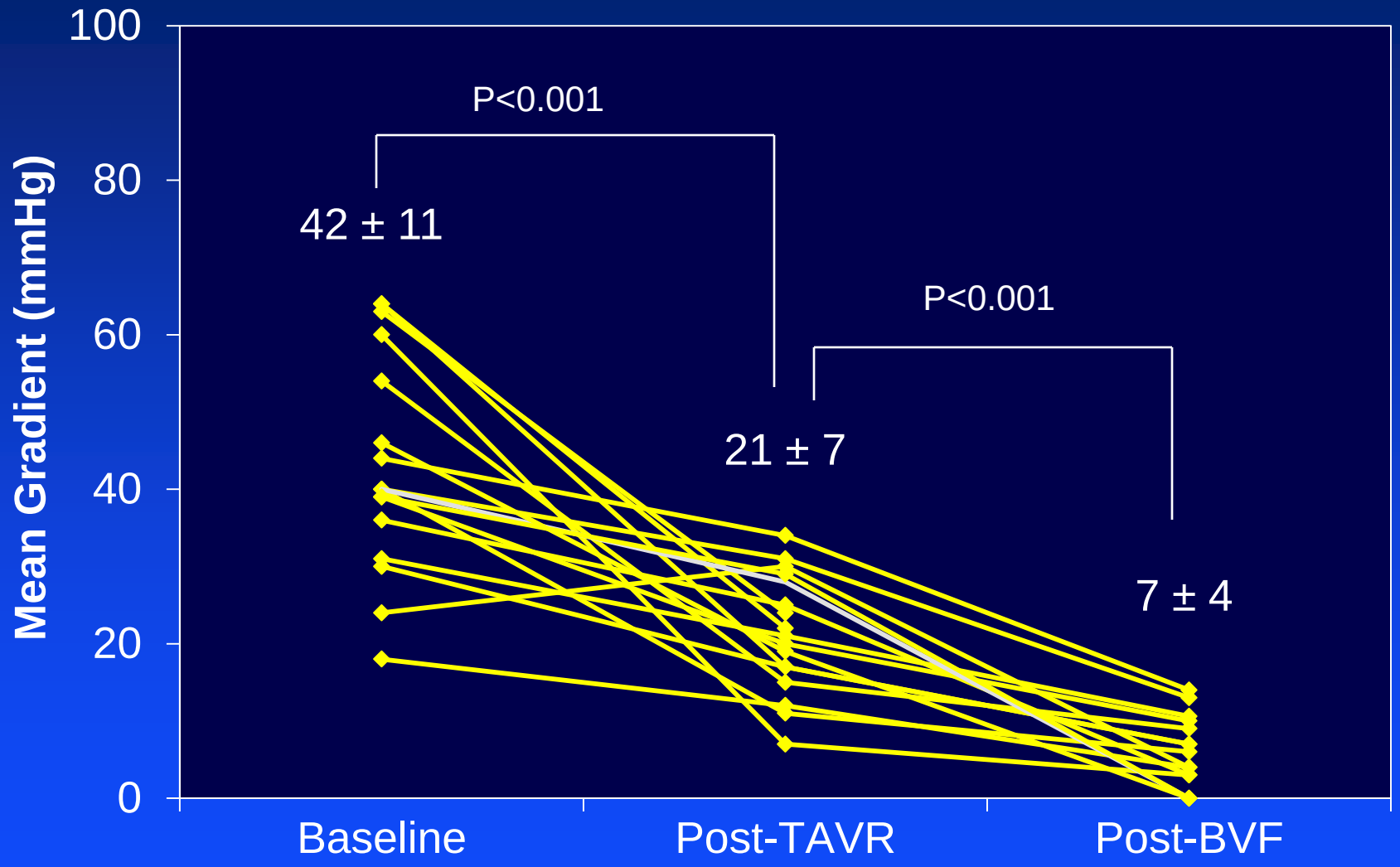
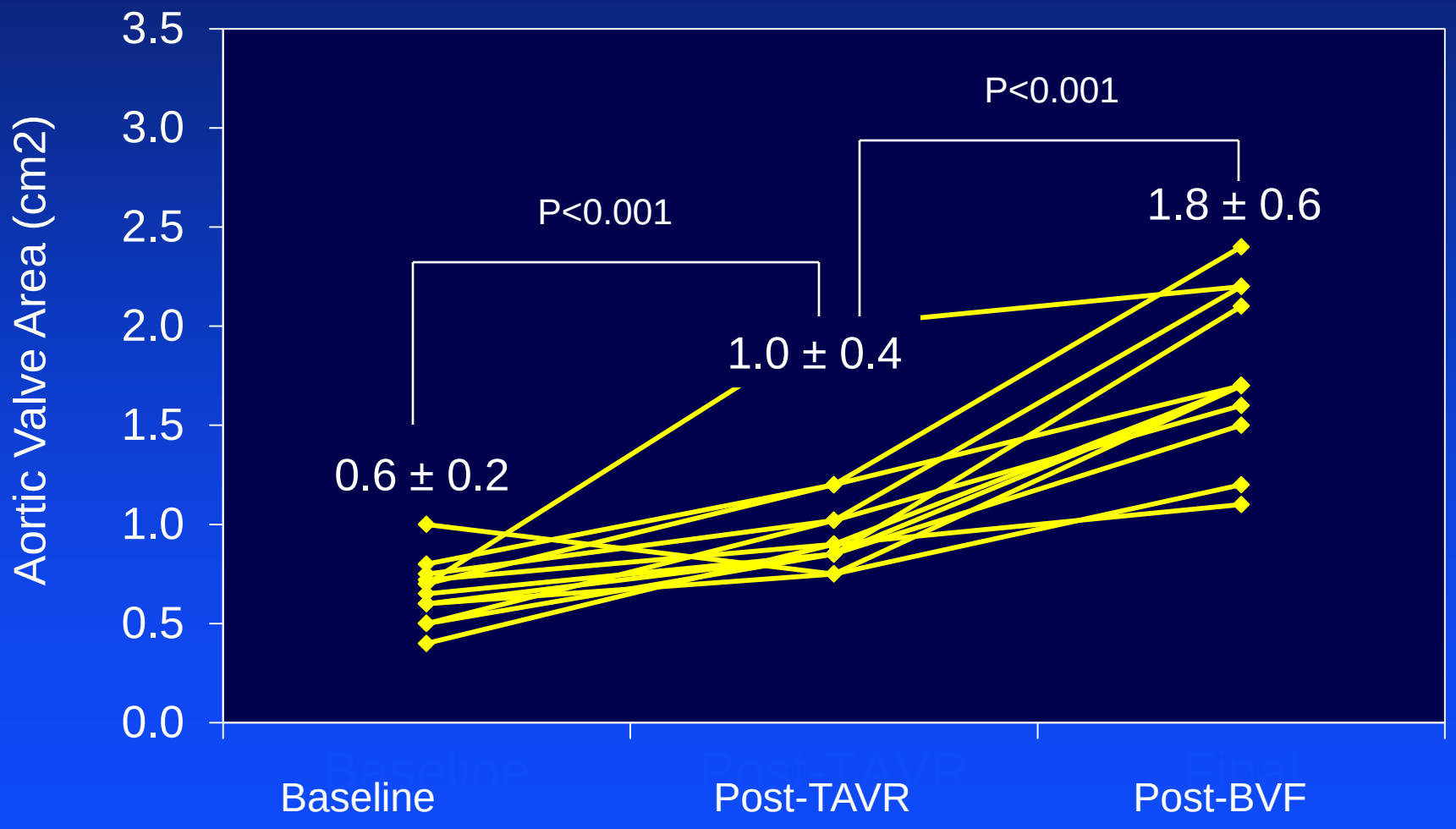
Mean Gradient



Effective Orifice Area (AVA)



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

BVF Complications (n=38)

- 1 minor stroke → no residual
- 1 chordal tear → moderate MR
- 1 severe AI from TAVR valve → treated with second valve-in-valve
- No in-hospital death
- No coronary occlusion
- No annular rupture (clinical or subclinical)
- No PPM

* 38 cases in full series as of 8/8/17

Intentional Fracture of Bioprosthetic Valves

- For patients with small bioprosthetic valves who are high risk for re-do AVR, this approach 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 the procedure is generally safe (although not entirely risk-free)
- 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*