Frequency and Safety of Bioprosthetic Valve Fracture in Patients Undergoing Valve-in-Valve TAVR for Failed Surgical Valves using SAPIEN 3/Ultra Valves: Insights From Real-World Data

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Disclosure Statement of Financial Interest

Within the last 24 months, I have financial relationships or affiliations with a manufacturer, marketer, reseller, or distributor of a healthcare product or service involved in the management of patients with any cardiovascular disease to include devices, drugs, and digital healthcare products listed below:

Affiliation/Financial Relationship	Companies
Consulting Fees/Honoraria/Speaker's Bureau	Boston Scientific Corporation, Edwards Lifesciences, Medtronic

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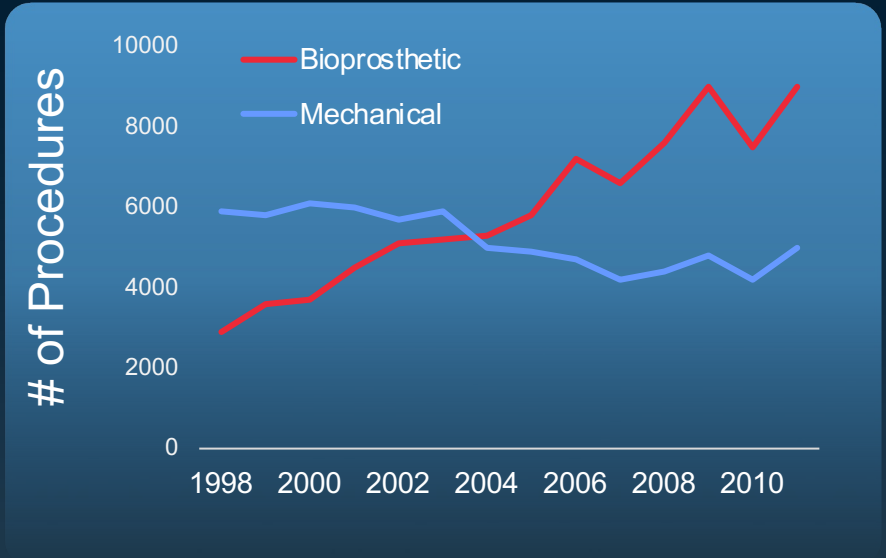
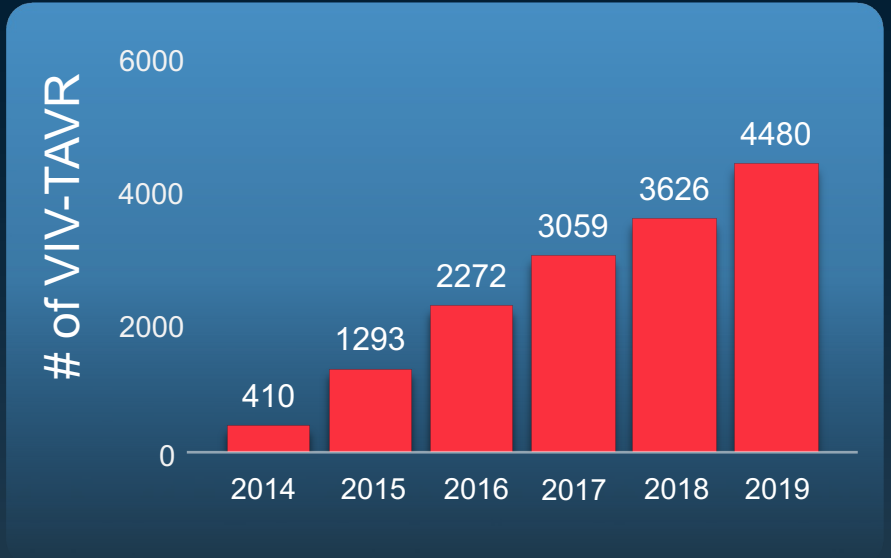
Increased Use of Bioprosthetic Valves and VIV-TAVR



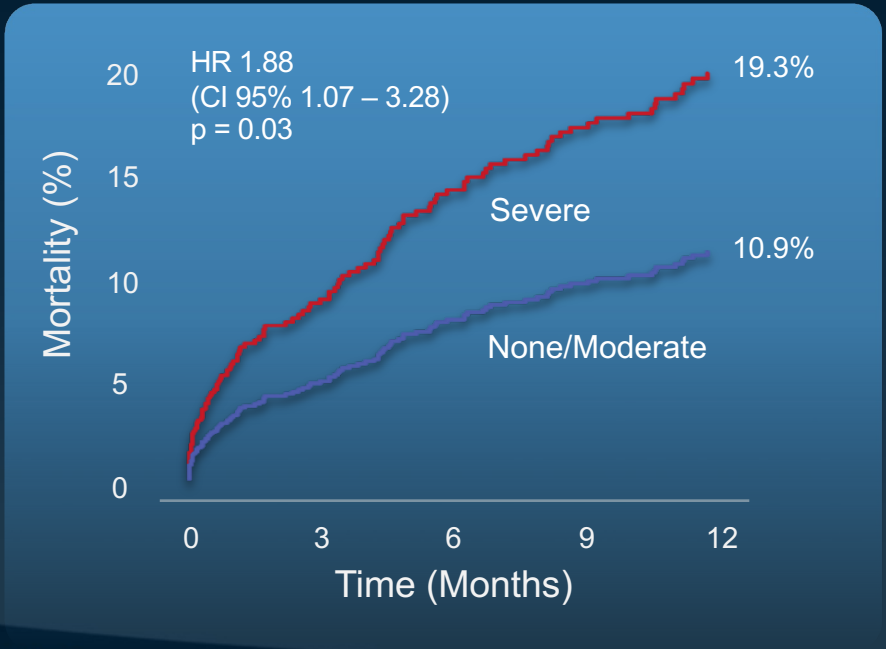


CRF TCT

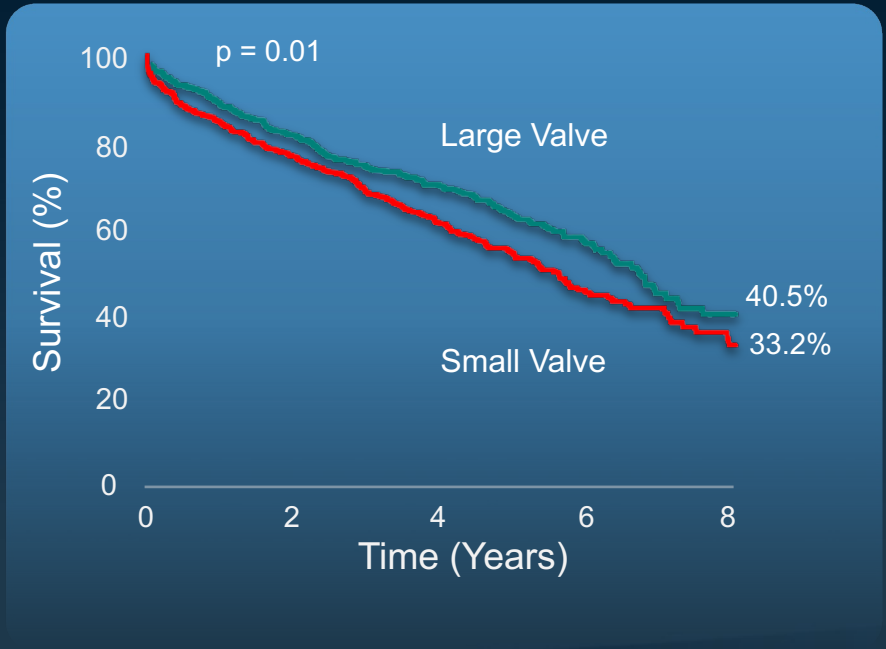
Isaacs A.J. et al. J Thorac Cardiovasc Surg. 2015 May and Carroll et al. JACC 2022

Prognosis After VIV TAVR: VIVID Registry

Pre-Existing PPM



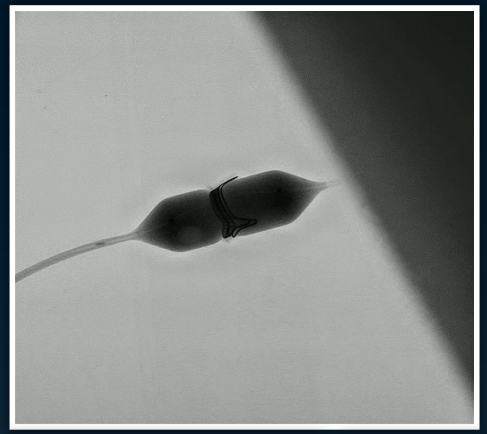
Small Surgical Valves



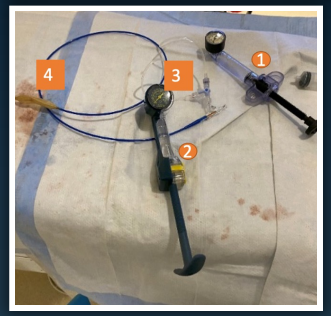
CRF TCT

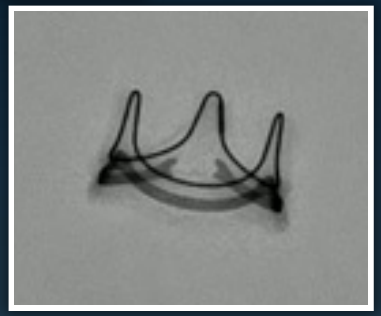
Pibarot et al. JACC Int 2018 and Bleiziffer – Dvir et al. *European Heart Journal* 2020

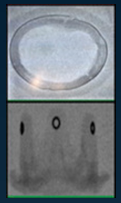
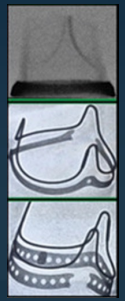
BVF Technique: How to do it?



- Intentional disruption of stent frame of the surgical heart valve
- To aid in THV expansion, improve mean gradients, increase effective orifice area





	Valve Size (mm)	TRU Balloon or Atlas Gold Pressure	Appearance After Fracture
St. Jude Trifecta	19 or 21	Not Fracturable	
St. Jude Biocor Epic	19 or 21	8 ATM	
Medtronic Mosaic	19 or 21	10 ATM	
Medtronic Hancock II	21	Not Fracturable	
Sorin Mitroflow	19 or 21	12 ATM	
Edwards MagnaEase	19 or 21	18 ATM	
Edwards Magna	19 or 21	24 ATM	

Allen et al. Ann Thoracic Surgery 2017

Gaps in Knowledge and Objective

Who Needs BVF?

- Patient selection
- All valves versus small surgical valves

How to define success?

- Gradients
- Outcomes
- Aortic valve area
- Long-term durability

When to perform BVF?

- Optimal timing
- Before versus after VIV-TAVR

Current experience is limited

- Small observational studies
- Limited and selected sites
- Lack of a control group

OBJECTIVE

To compare the safety and efficacy of VIV-TAVR with or without BVF

Methods

Study Population

Patients who underwent VIV-TAVR with SAPIEN 3 or SAPIEN 3 Ultra (S3/U) between December 2020 and March 2022 and included in the TVT Registry were identified

Analyses

1-BVF attempted vs BVF not attempted

2- BVF attempted *before* VIV-TAVR vs. BVF attempted *after* VIV-TAVR

Outcomes

Safety

All-cause in-hospital mortality

Hemodynamic

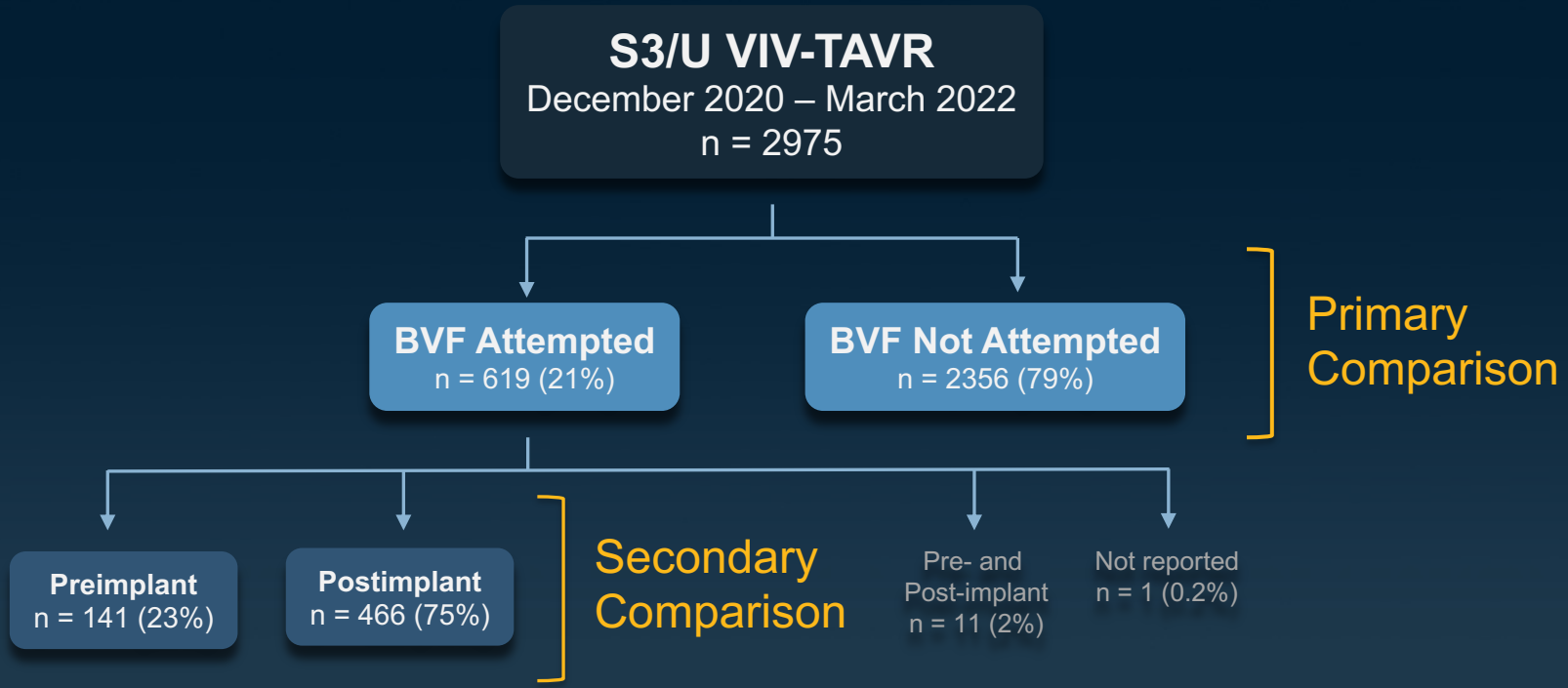
Echocardiographic aortic valve area and mean gradient

Statistical Methods

- **Inverse probability of treatment weighting** (IPTW) for average treatment effect among the treated (ATT) was used to adjust for potential confounders
- **36 covariates** were included in the model to evaluate **safety outcomes**
- **True internal diameter** of the failed surgical valve was also included in evaluating **hemodynamic outcomes**

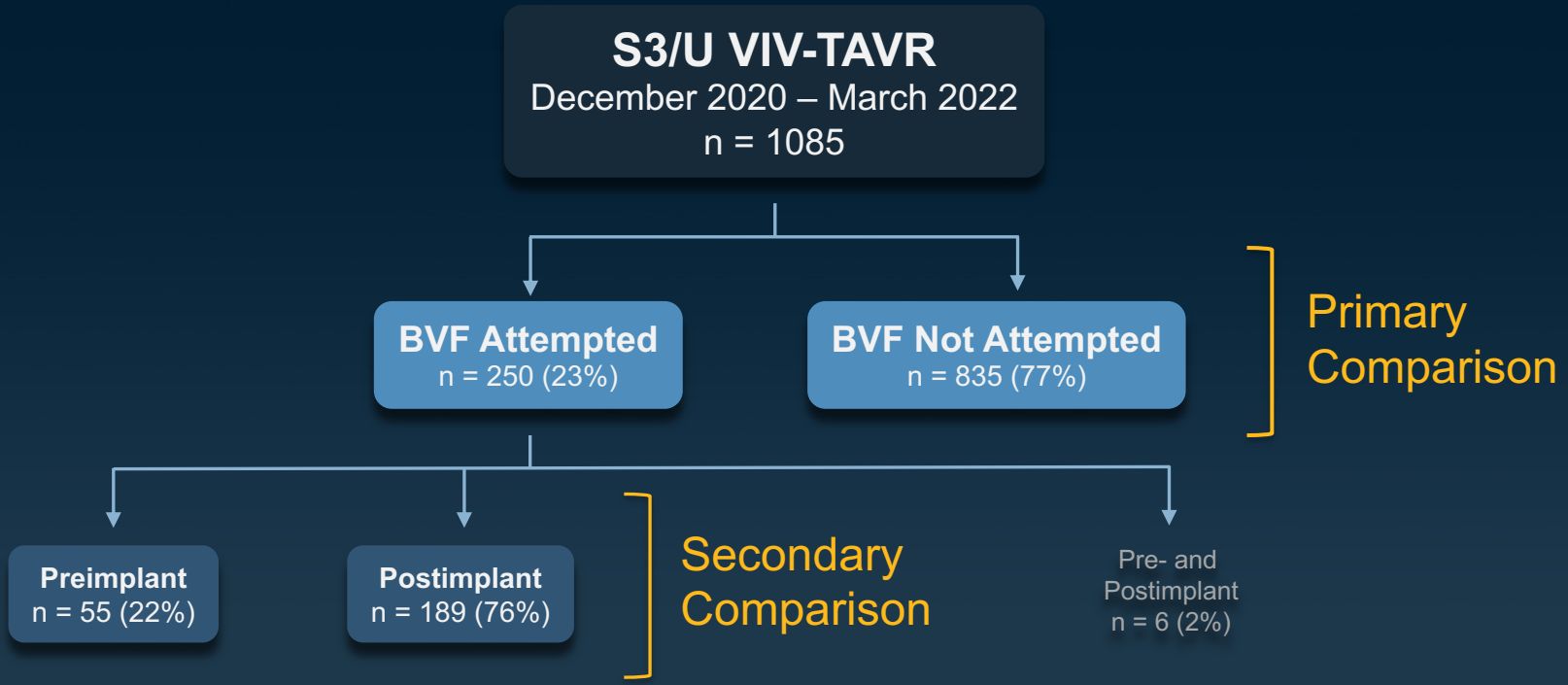
*Covariates: age, race, sex (male), body mass index, access site, prior PCI, prior CABG, prior stroke, carotid stenosis, peripheral arterial disease, hypertension, diabetes, chronic lung disease, immunocompromise, porcelain aorta, atrial fibrillation, creatinine, hemoglobin level, estimated GFR, aortic valve mean gradient, LVEF, aortic regurgitation, mitral regurgitation, tricuspid regurgitation, NYHA functional class III/IV, 5-meter walk test, KCCQ-OS score, currently on dialysis, pacemaker, previous ICD, cardiogenic shock w/in 24hr, current/recent smoker, prior TIA, prior surgical repair, endocarditis, and primary indication for VIV-TAVR

Study Flow: Safety Outcomes

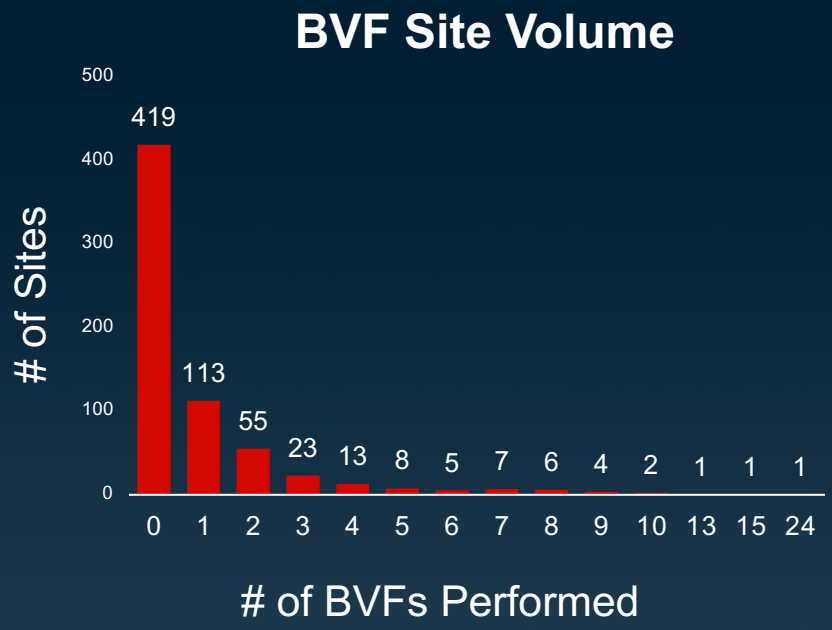


Study Flow: Echocardiographic Outcomes

Includes only patients with known true internal diameter of surgical valve



Frequency of BVF in VIV-TAVR in the United States



Frequency

- 239/658 VIV-TAVR sites performed BVF
- 35 sites performed ≥5 BVFs
- 5 sites performed ≥10 BVFs

Timing

- 81 sites performed pre-implant BVF
- 42/239 (18%) sites exclusively performed pre-implant BVF

VIV-TAVR Experience

- Of the 26 institutions that performed BVF at a rate of 50% or higher in their VIV-TAVR patients, the median number of VIV-TAVR procedures was 2.

CRF TCT

Prior surgical valve size available for 1085 patients (Known True ID cohort)

Baseline Patient Characteristics - Unadjusted

	Attempted (n = 619)	Not Attempted (n = 2356)	P-value
Age, yrs	73.7 ± 9.9	73.3 ± 11.2	0.45
Male	69.3%	70.7%	0.49
STS Risk Score	5.1 ± 4.1	5.6 ± 5.8	0.01
NYHA Class III/IV	74.2%	75.1%	0.67
BMI (kg/m^2)	29.6 ± 6.7	29.3 ± 10.1	0.54
Hypertension	90.0%	87.7%	0.12
Diabetes	34.4%	30.8%	0.08
Atrial fibrillation/flutter	40.4%	46.2%	0.01
Prior stroke	12.8%	12.6%	0.89
Prior CABG	38.1%	31.0%	<0.01
Prior PCI	24.2%	21.1%	0.09
Cardiogenic shock w/in 24 hrs	1.9%	4.5%	<0.01
Baseline pacemaker	12.9%	16.7%	0.02
Carotid stenosis	15.1%	12.0%	0.04
Estimated GFR (mL/min/1.73m^2)	64.1 ± 25.1	61.8 ± 24.0	0.03

Statistically different

Baseline Patient Characteristics - Adjusted

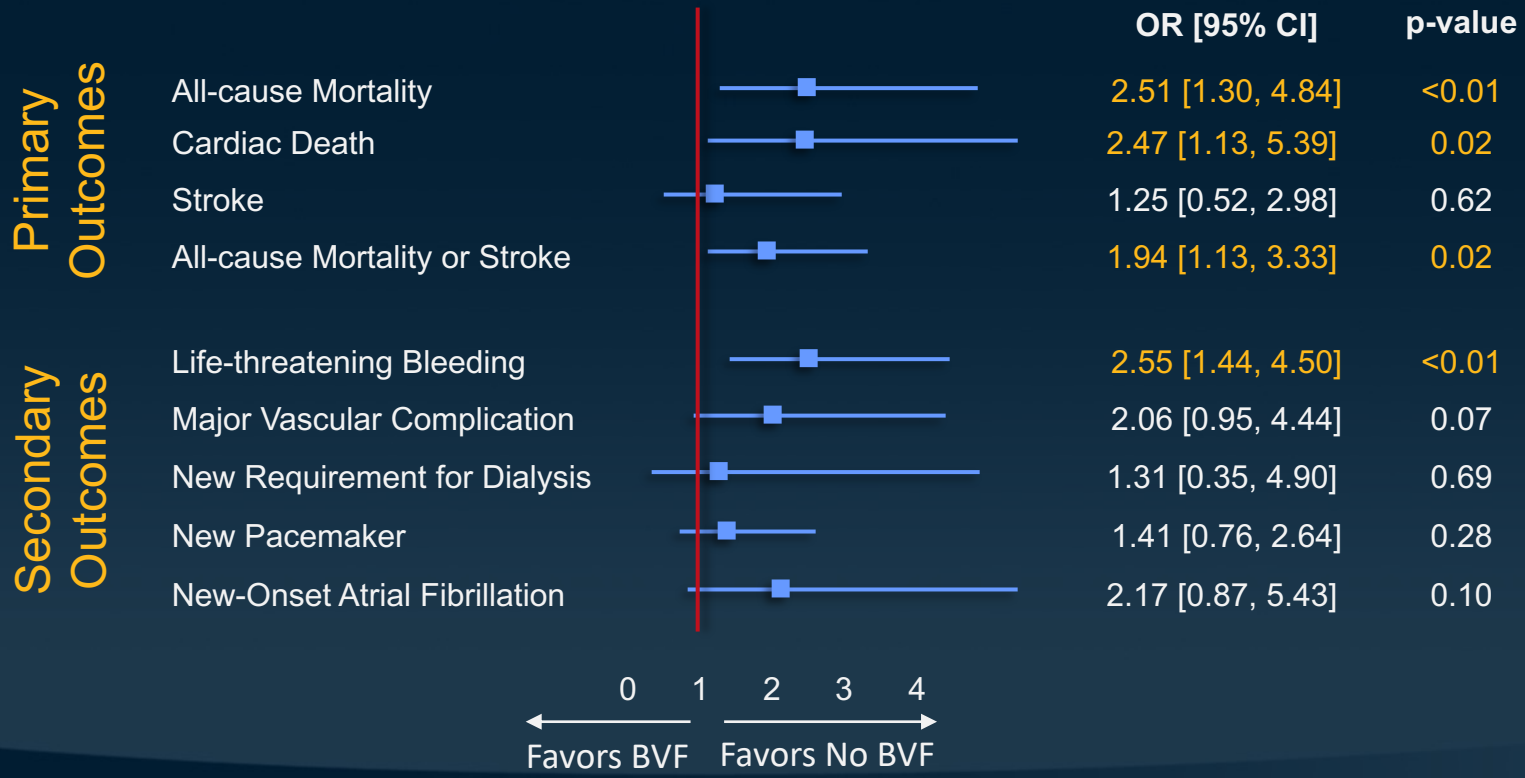
	Attempted (n = 619)	Not Attempted (n = 2356)	P-value
Age, yrs	73.7	73.7	0.97
Male	69.3%	68.8%	0.82
STS Risk Score	5.1	5.4	0.20
NYHA Class III/IV	74.3%	74.0%	0.88
BMI (kg/m^2)	29.5	29.5	0.90
Hypertension	90.0%	90.1%	0.96
Diabetes	34.4%	34.2%	0.91
Atrial fibrillation/flutter	40.4%	40.5%	0.95
Prior stroke	12.8%	13.1%	0.85
Prior CABG	38.1%	38.0%	0.94
Prior PCI	24.2%	23.7%	0.79
Cardiogenic shock w/in 24 hrs	1.9%	2.0%	0.95
Baseline pacemaker	12.9%	12.8%	0.93
Carotid stenosis	15.0%	15.0%	0.98
Estimated GFR ($mL/min/1.73m^2$)	64.1%	64.0%	0.93

Baseline Echo & Procedural Details

Baseline Echocardiography	Attempted (n = 619)	Not Attempted (n = 2356)	P-value
Aortic insufficiency (mod/sev)	42.1%	52.3%	<0.01
AV Area (cm^2)	0.85 ± 0.37	0.90 ± 0.45	0.01
AV mean gradient	40.5 ± 15.1	39.4 ± 16.9	0.16
LVEF (%)	55.1 ± 11.8	52.3 ± 13.0	<0.01
Procedural Details			
Transfemoral access	95.8%	95.5%	0.71
Conscious sedation	51.6%	49.6%	0.38
Procedure time (min)	78.5 ± 38.5	75.0 ± 58.8	0.07
Contrast volume	52.1 ± 50.0	56.3 ± 54.1	0.09
Implant success	98.7%	99.0%	0.56

Unadjusted

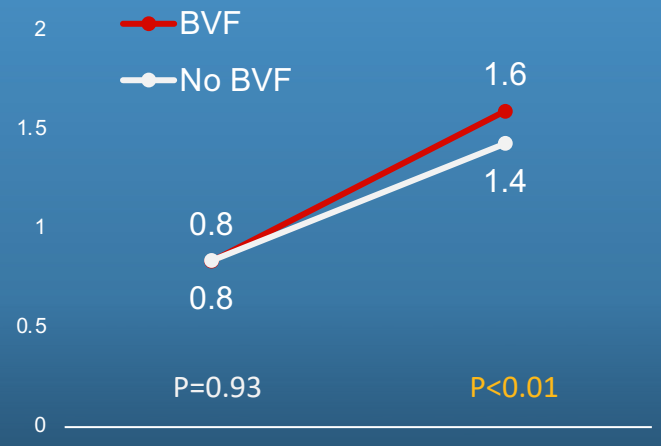
In-Hospital Safety Outcomes: BVF vs No BVF



IPTW Adjusted, Significantly different

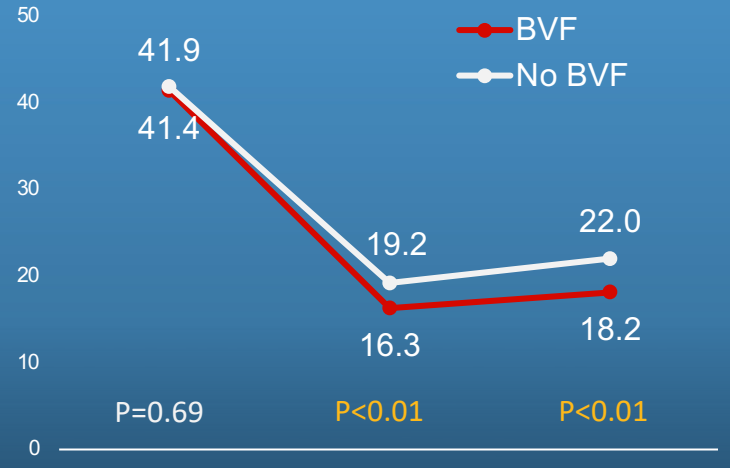
Echocardiographic Outcomes*: BVF vs No BVF

Aortic Valve Area (cm^2)



	Baseline	Discharge
BVF	n = 223	n = 185
No BVF	n = 673	n = 656

Mean Valve Gradient (mm Hg)

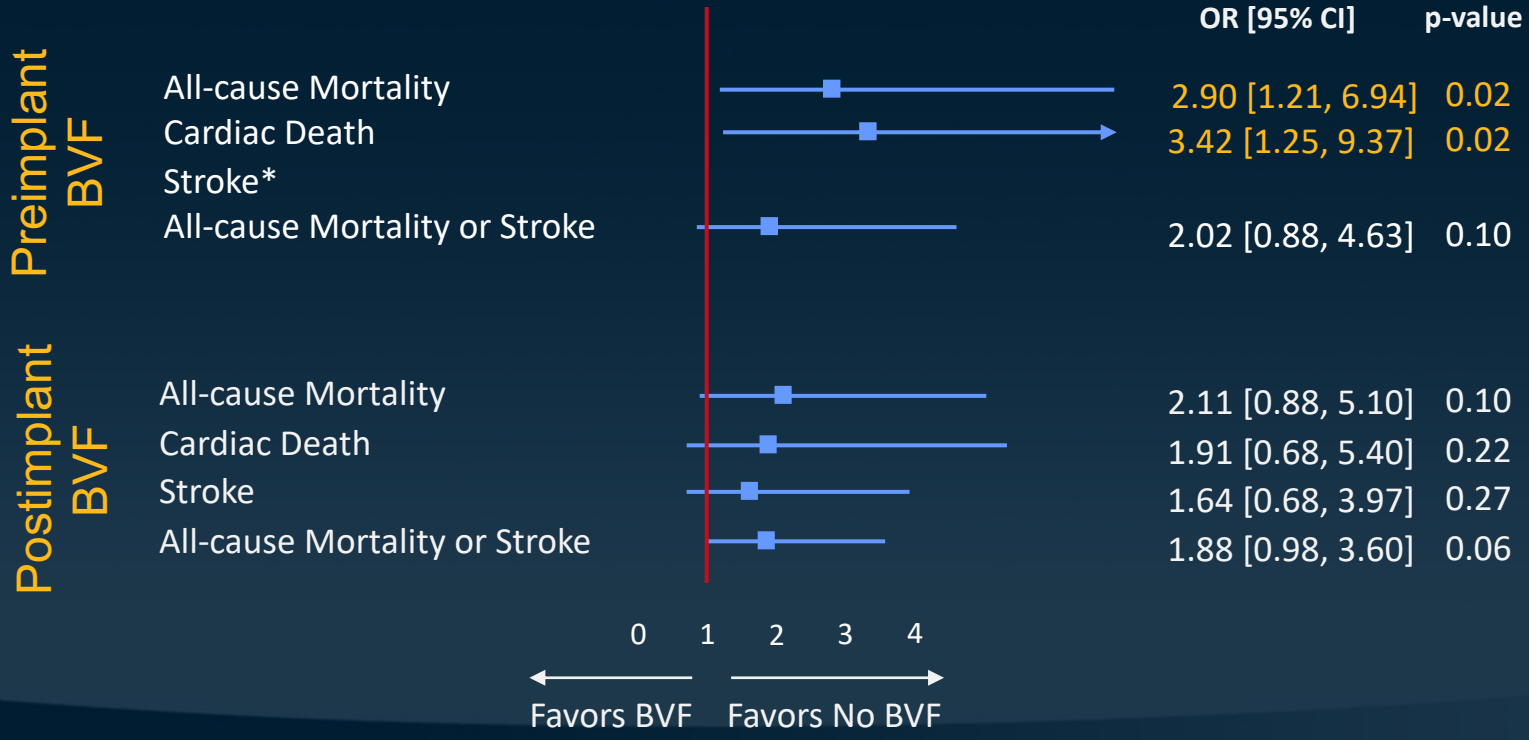


	Baseline	Discharge	30 Days
BVF	n = 250	n = 225	n = 171
No BVF	n = 835	n = 779	n = 611

CRF TCT

IPTW Analysis; Hemodynamic outcomes are adjusted, patient n are unadjusted
True ID was an additional covariate for adjusted hemodynamic outcomes

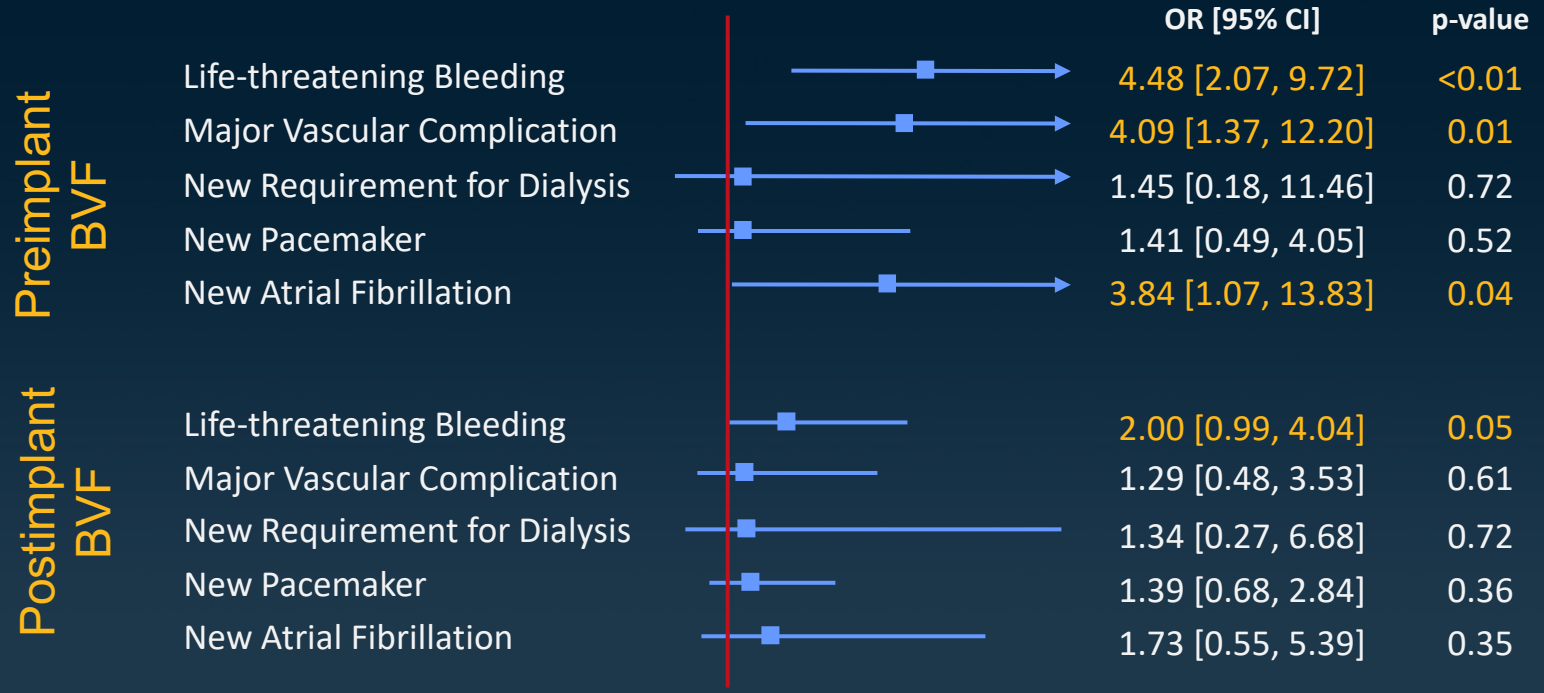
In-hospital Safety Outcomes: Preimplant and Postimplant BVF



IPTW Adjusted, Significantly different

*No stroke observed in the preimplant cohort

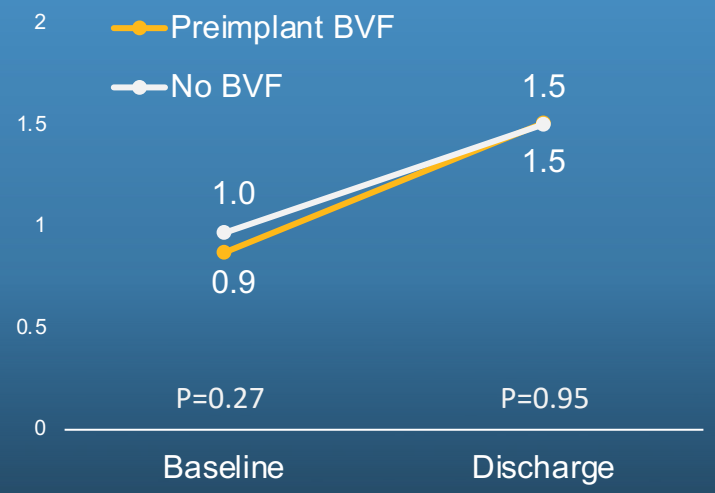
In-hospital Safety Outcomes: Preimplant and Postimplant BVF



IPTW Adjusted, Significantly different

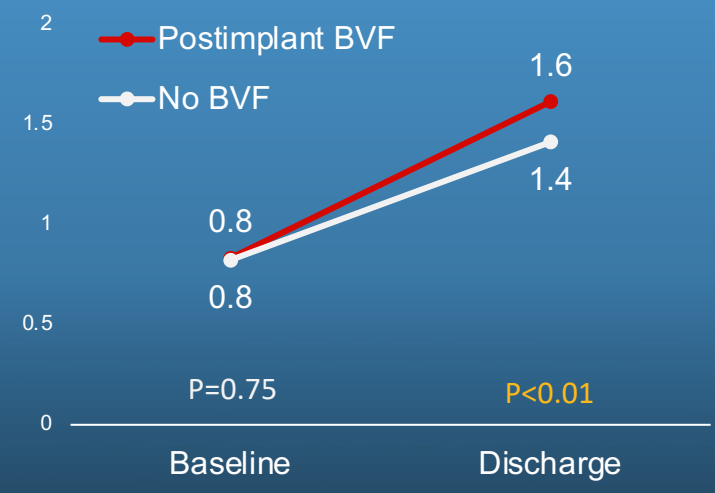
Aortic Valve Area (cm^2): Preimplant and Postimplant BVF

Preimplant vs No BVF



Preimplant	n = 45	n = 38
No BVF	n = 673	n = 656

Postimplant vs No BVF

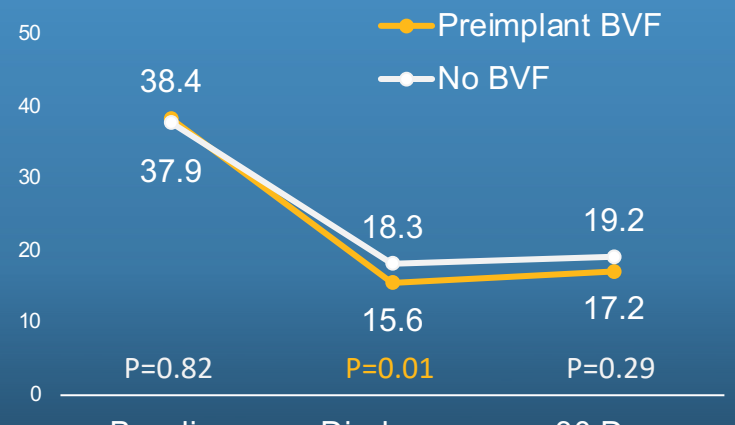


Postimplant	n = 173	n = 144
No BVF	n = 673	n = 656

IPTW Analysis; Hemodynamic outcomes are adjusted, patient n are unadjusted
*True ID was an additional covariate for adjusted hemodynamic outcomes

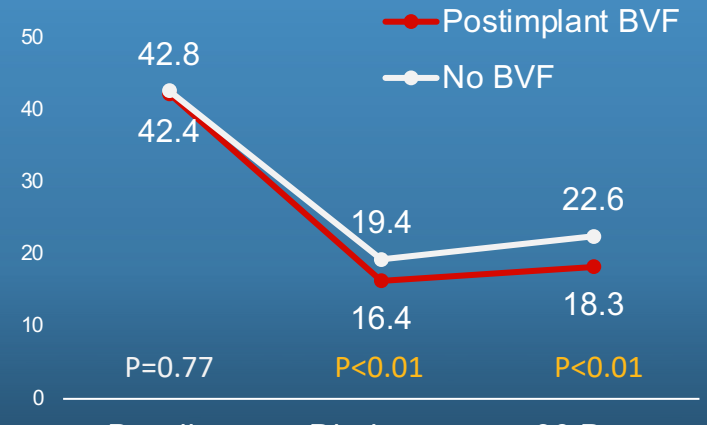
Mean Valve Gradient (mmHg): Preimplant and Postimplant BVF

Preimplant vs No BVF



	Baseline	Discharge	30 Days
Preimplant	n = 55	n = 49	n = 35
No BVF	n = 835	n = 779	n = 611

Postimplant vs No BVF



	Baseline	Discharge	30 Days
Postimplant	n = 189	n = 171	n = 133
No BVF	n = 835	n = 779	n = 611

IPTW Analysis; Hemodynamic outcomes are adjusted, patient n are unadjusted
*True ID was an additional covariate for adjusted hemodynamic outcomes

Study Limitations

- Observational study; subject to bias and confounding
- Decision to perform and timing of BVF not randomized
- Lack of independent core laboratory to adjudicate successful BVF
- True ID information only available for Edwards Lifesciences SHV
- Echocardiographic vs. Cath Gradients
- Follow-up time insufficient to assess clinical benefit of BVF
- Results should be considered hypothesis-generating

Conclusions

In contemporary U.S. experience with BVF as an adjunct to S3/U ViV-TAVR, BVF was associated with:

- Early hazard of in-hospital mortality
- Risk of mortality appears higher when BVF is performed prior to ViV-TAVR
- Modest differences in echocardiographic gradients and aortic valve area – far less than previously reported
- Long-term risk/benefit of BVF needs to be further characterized
- Opportunity to standardize BVF indications, technique and post-procedural management

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