



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



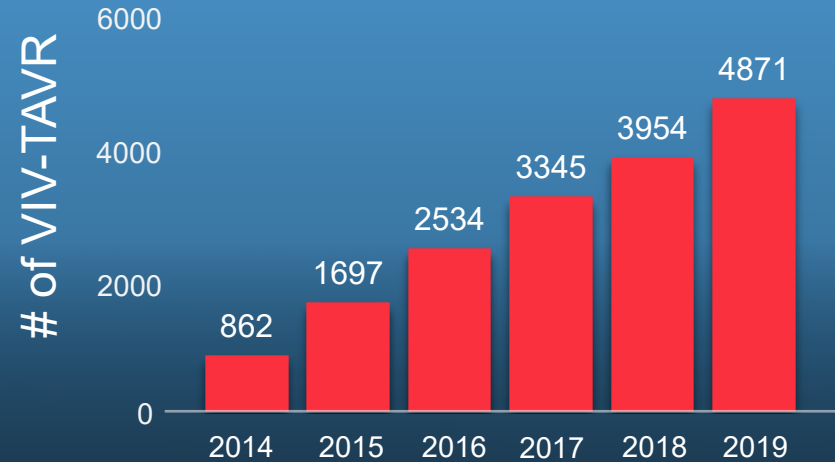
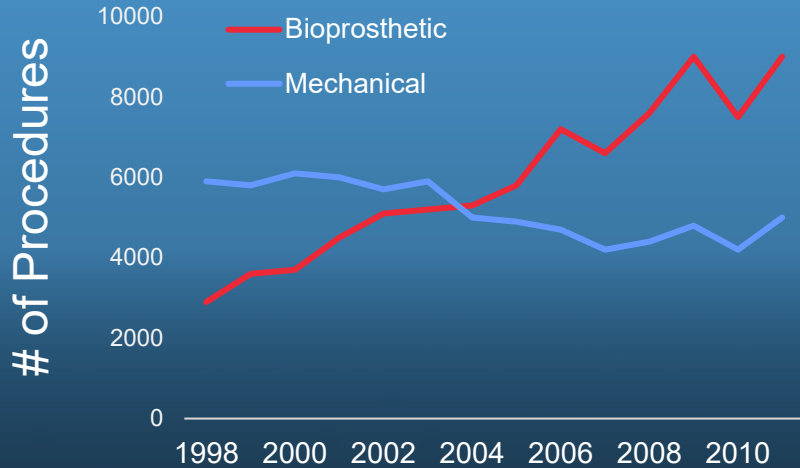
TCT

SEPTEMBER 16-19, 2022
BOSTON CONVENTION AND EXHIBITION CENTER
BOSTON, MA

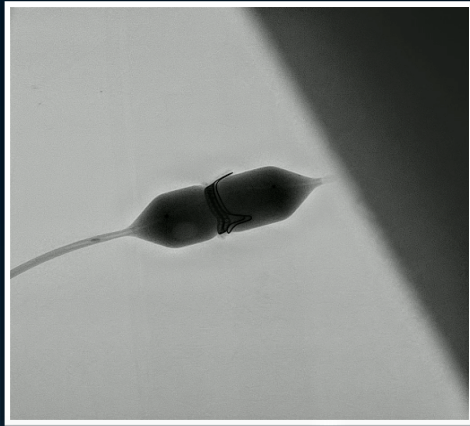
Santiago Garcia, MD

Vinayak Bapat, MD, Jeremiah P. Depta, MD, Evelio Rodriguez, MD, Vinod H. Thourani, MD, Brian K. Whisenant, MD, Firas Zahr, MD, Adnan K. Chhatriwalla, MD, Keith B. Allen, MD

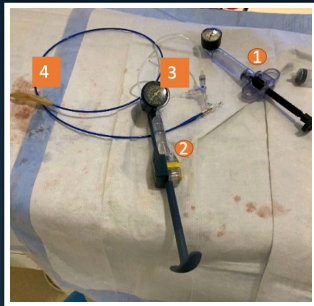
Increased Use of Bioprosthetic Valves and VIV-TAVR



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 Model	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	

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

BVF attempted vs BVF not attempted

BVF attempted before VIV-TAVR
BVF attempted after VIV-TAVR

Outcomes

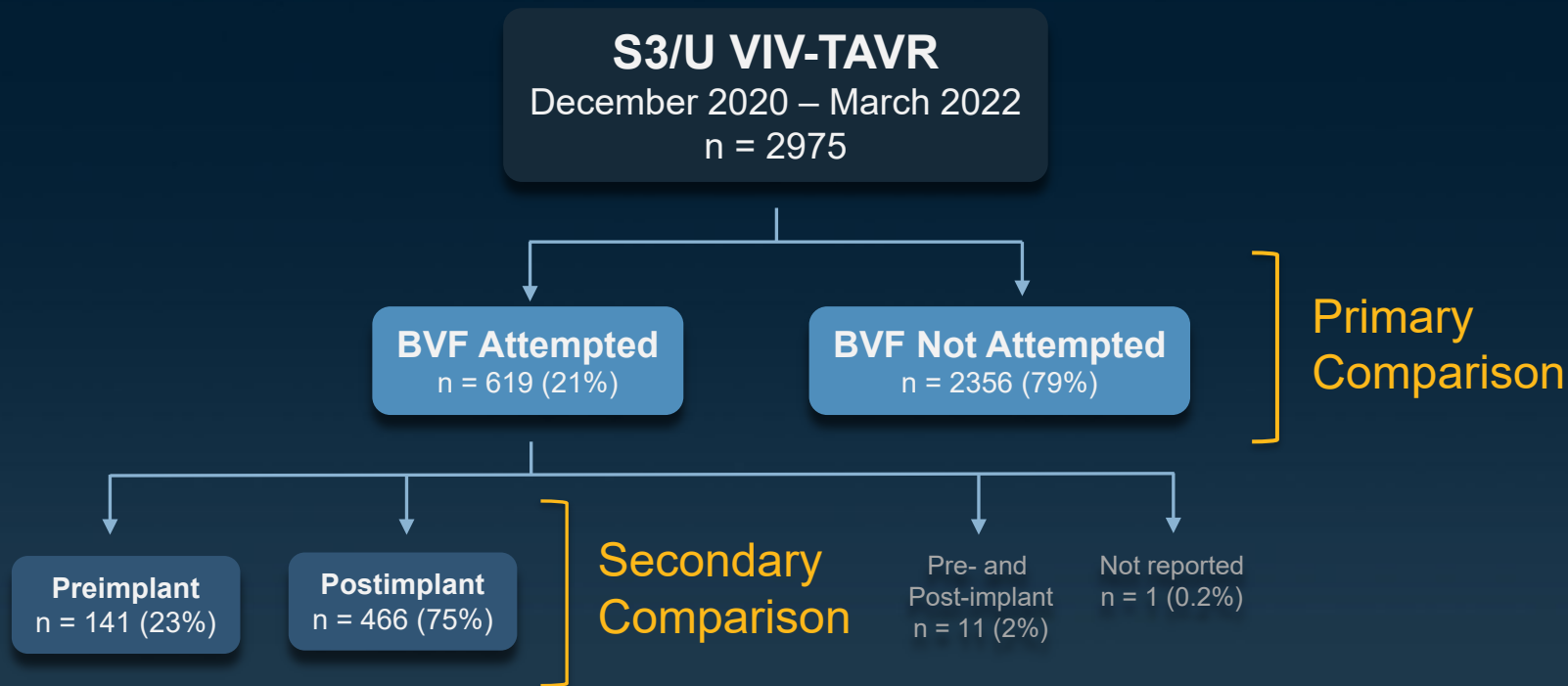
Safety

All-cause in-hospital mortality

Hemodynamic

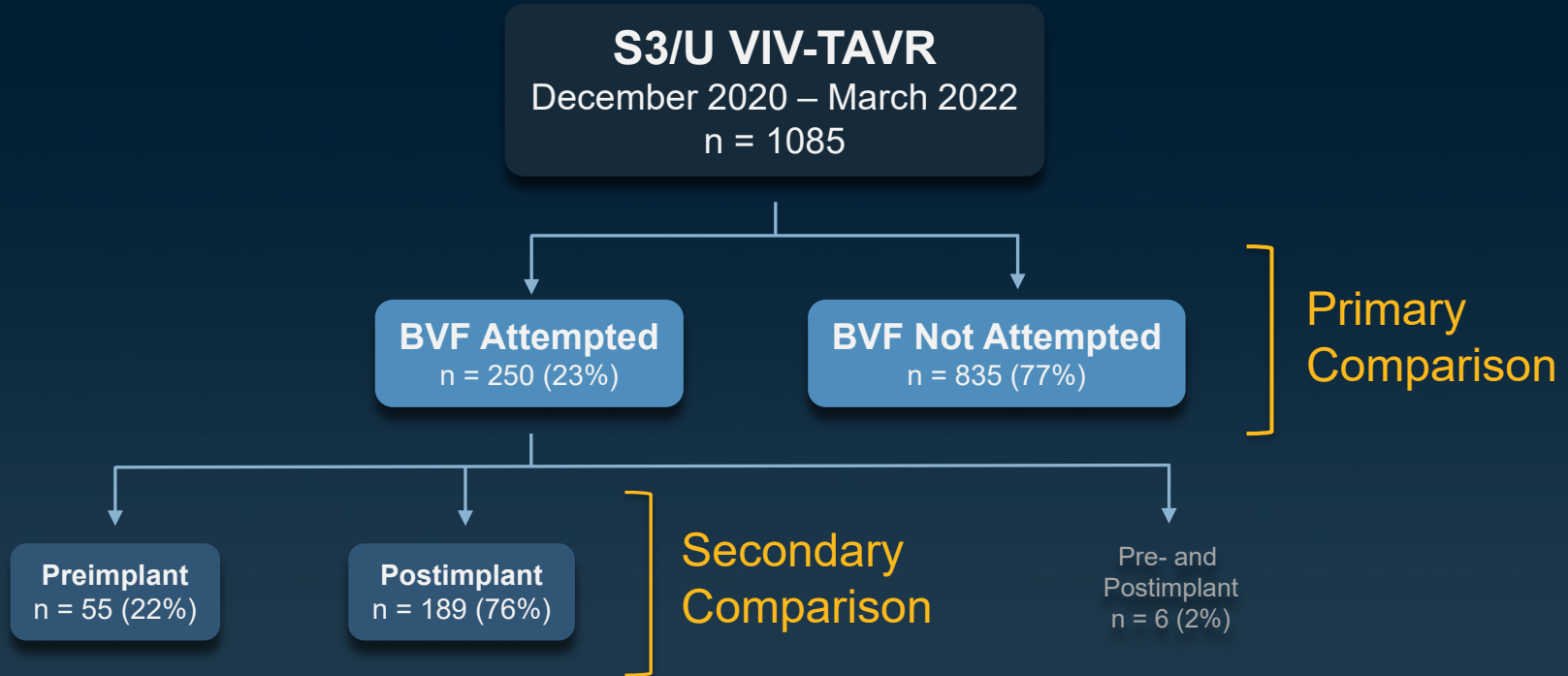
Echocardiographic aortic valve area and mean gradient

Study Flow: Safety Outcomes

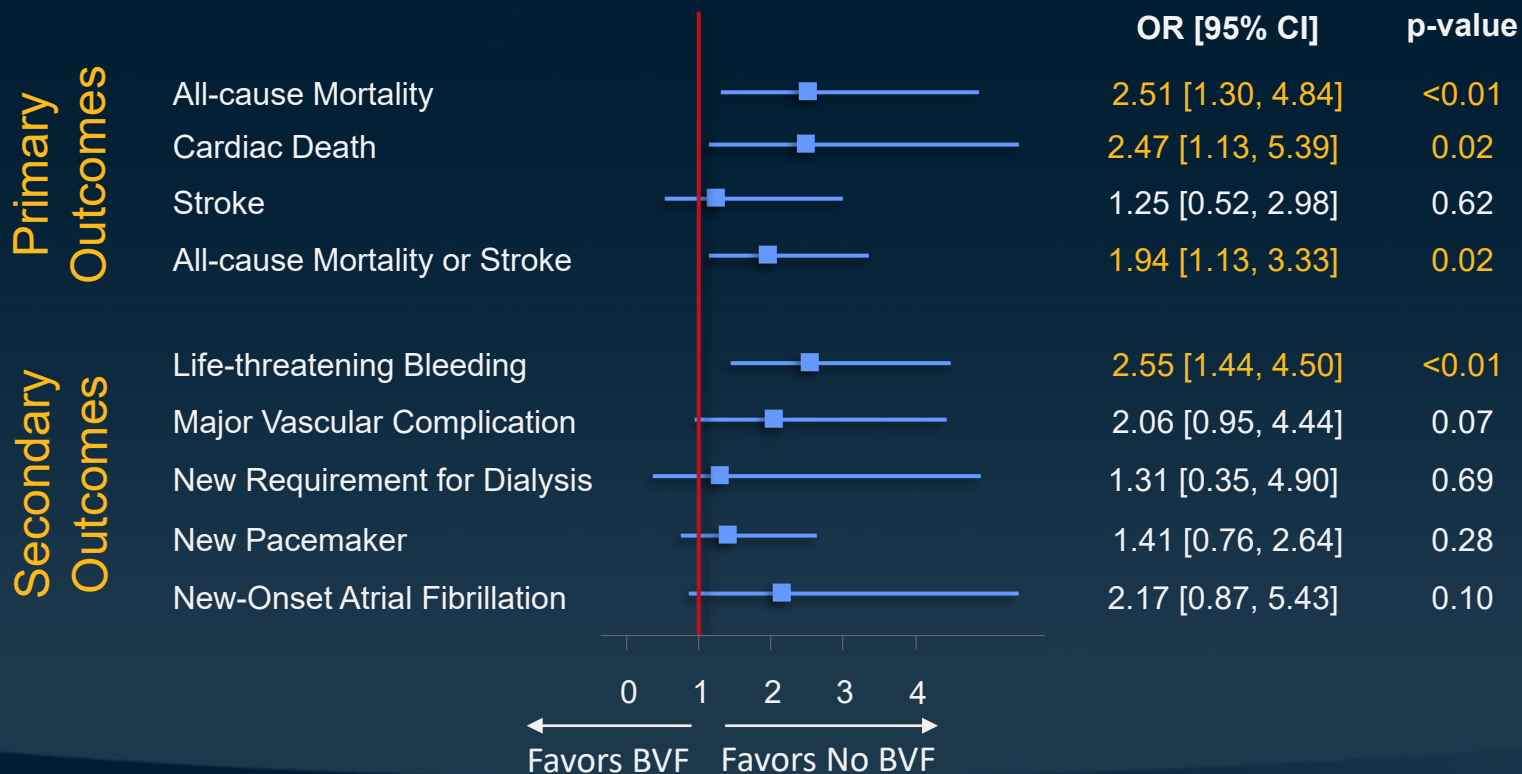


Study Flow: Echocardiographic Outcomes

Includes only patients with known true internal diameter of surgical valve

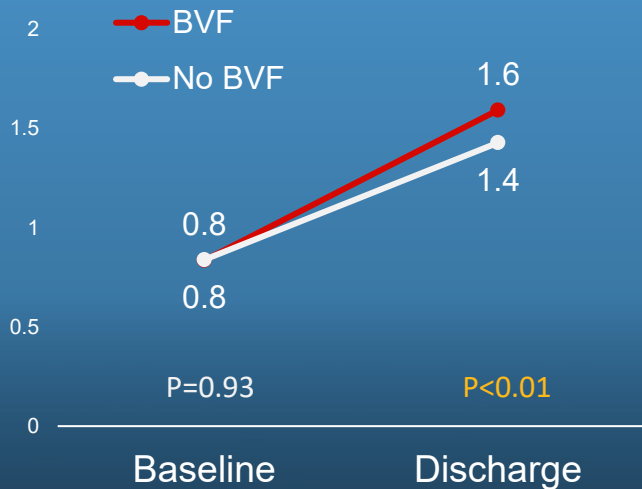


In-Hospital Safety Outcomes: BVF vs No BVF



Echocardiographic Outcomes*: BVF vs No BVF

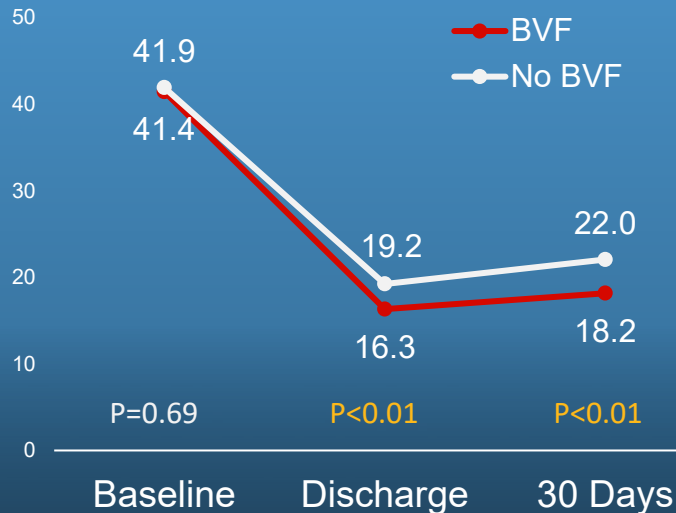
Aortic Valve Area (cm²)



BVF n = 223
No BVF n = 673

n = 185
n = 656

Mean Valve Gradient (mm Hg)

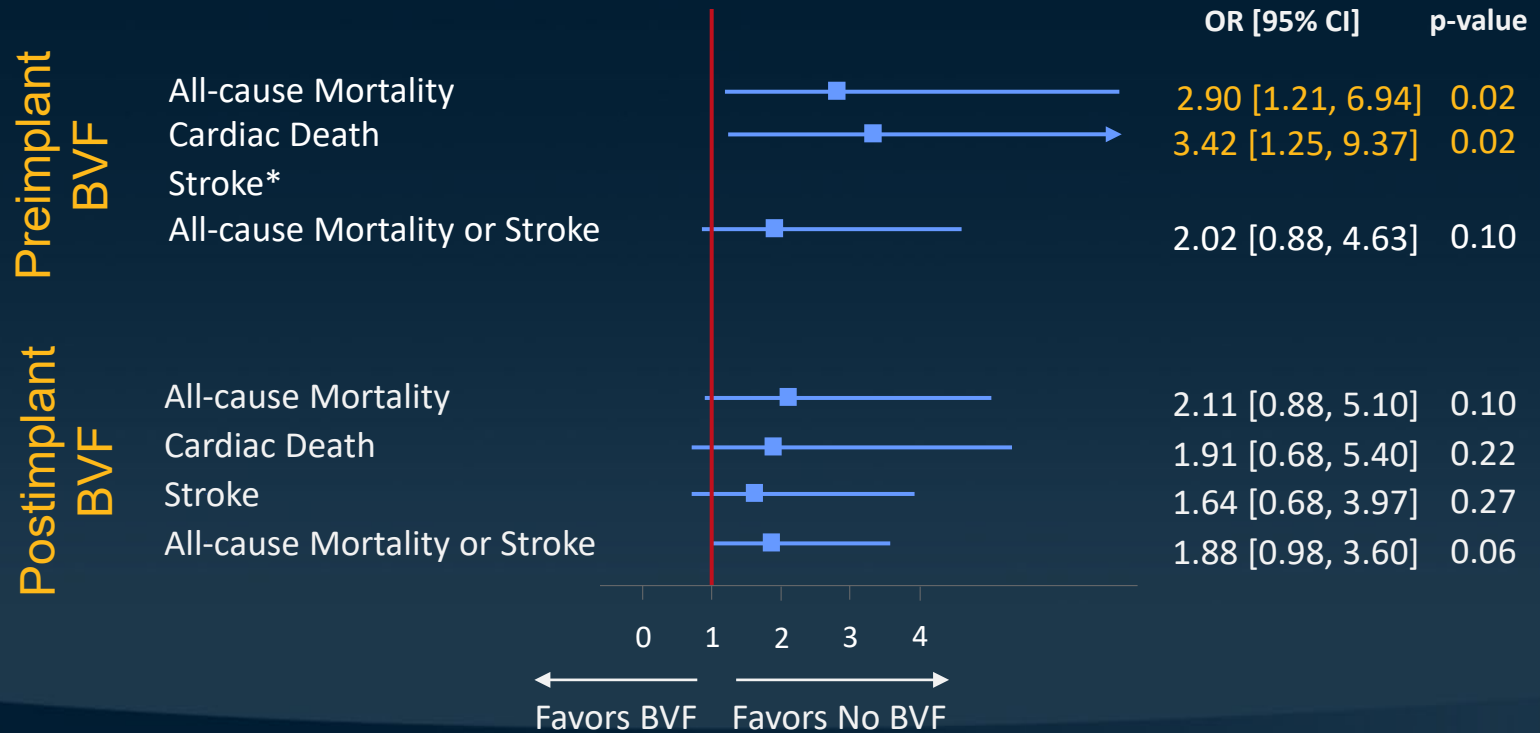


BVF n = 250
No BVF n = 835

n = 225
n = 779

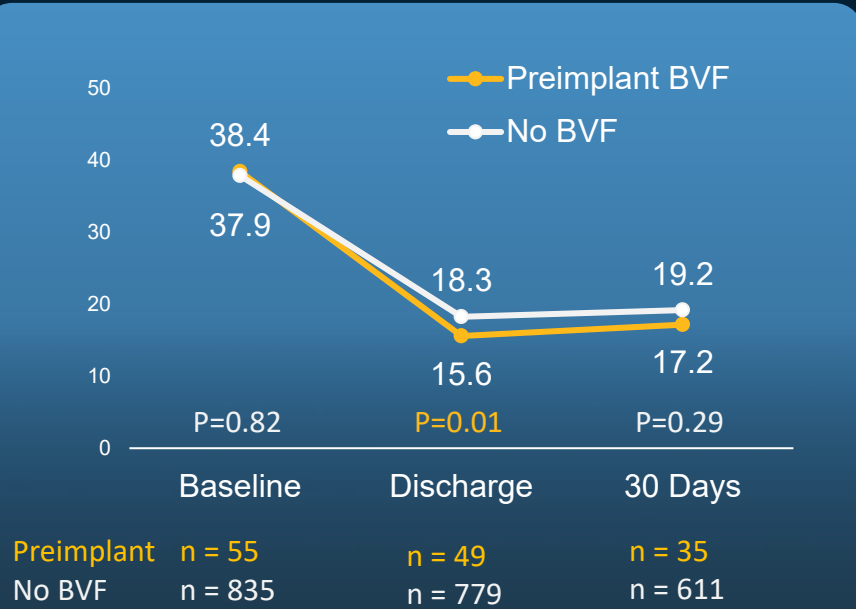
n = 171
n = 611

In-hospital Safety Outcomes: Preimplant and Postimplant BVF

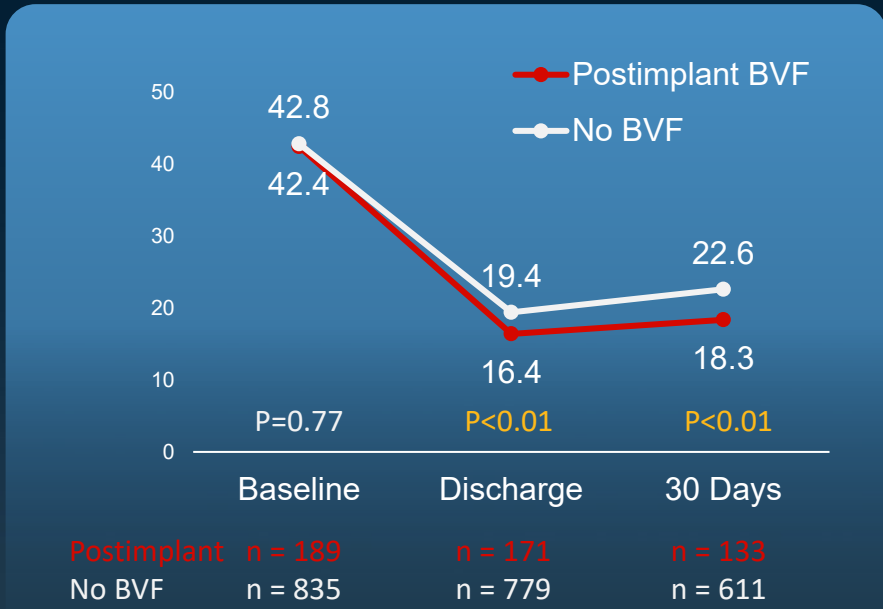


Mean Valve Gradient (mmHg): Preimplant and Postimplant BVF

Preimplant vs No BVF



Postimplant vs No BVF



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



CRF®

TCT

SEPTEMBER 16-19, 2022
BOSTON CONVENTION AND EXHIBITION CENTER
BOSTON, MA

Santiago Garcia, MD

The Christ Hospital, Cincinnati, OH

Vinayak Bapat, MD

Abbott Northwestern Hospital, Minneapolis, MN

Jeremiah P. Depta, MD

Sands-Constellation Heart Institute/Rochester General
Hospital, Rochester, NY

Evelio Rodriguez, MD

Ascension Medical Group, Nashville, TN

Vinod H. Thourani, MD

Piedmont Heart Institute, Atlanta, GA

Brian K. Whisenant, MD

Intermountain Medical Center, Salt Lake City, UT

Firas Zahr, MD

Oregon Health and Science University, Portland, OR

Adnan K. Chhatrwalla, MD

St. Luke's Mid America Heart Institute and University of
Missouri, Kansas City, MO

Keith B. Allen, MD

St. Luke's Mid America Heart Institute and University of
Missouri, Kansas City, MO

santiagogarcia@me.com