Bioprosthetic Valve Fracture (BVF) During VIV TAVR with an Evolut Valve: Safety and Hemodynamic Outcomes from the TVT Registry

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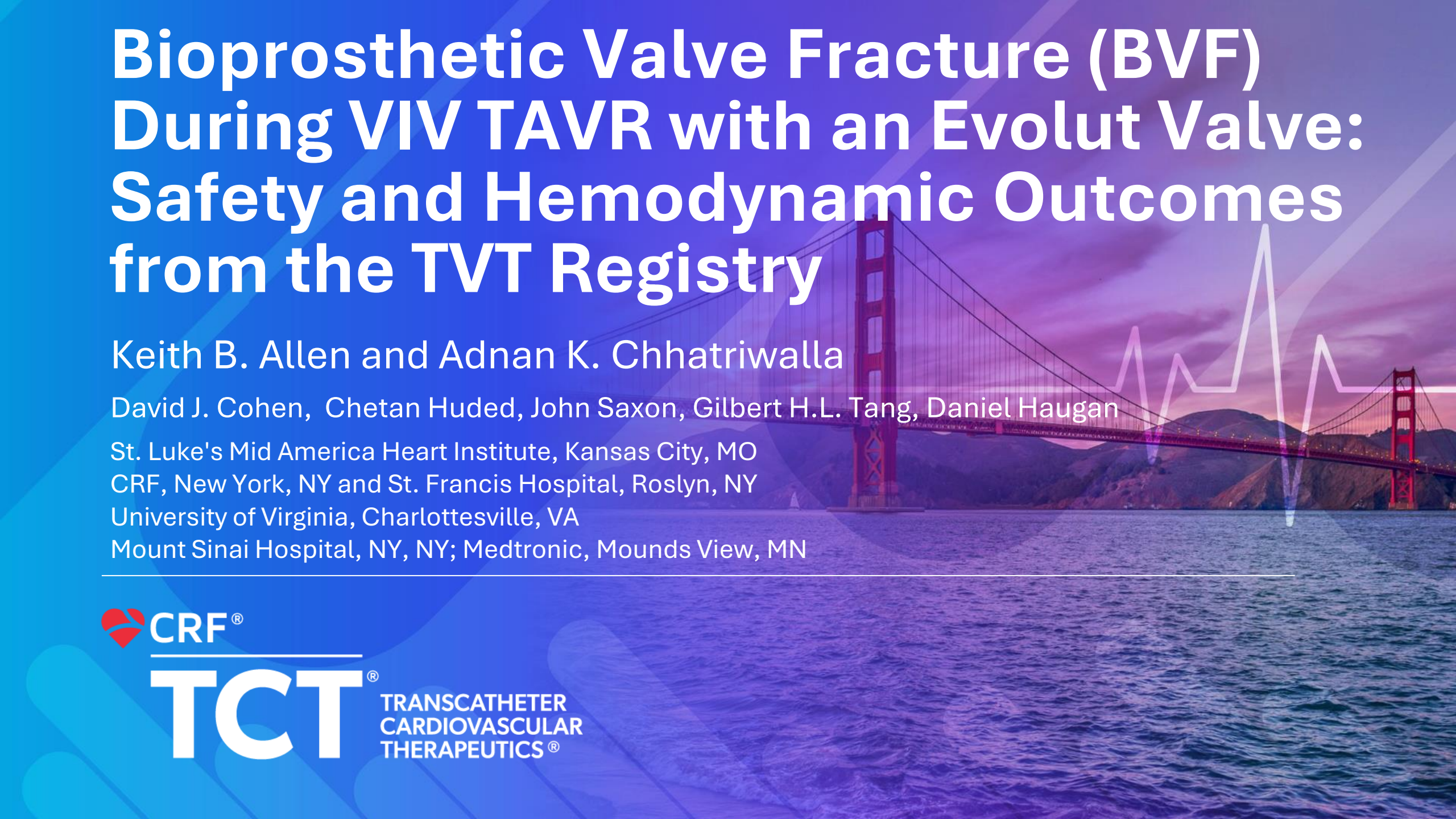

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Disclosure of relevant financial relationships

- Within the prior 24 months, I have had a financial relationship with the organization(s) listed below:

Nature of Financial Relationship	Ineligible Company
Research support, proctor fees, and consulting fees with all payments to St. Luke's Hospital	Abbott Vascular, Edwards Lifesciences, Medtronic, and Boston Scientific

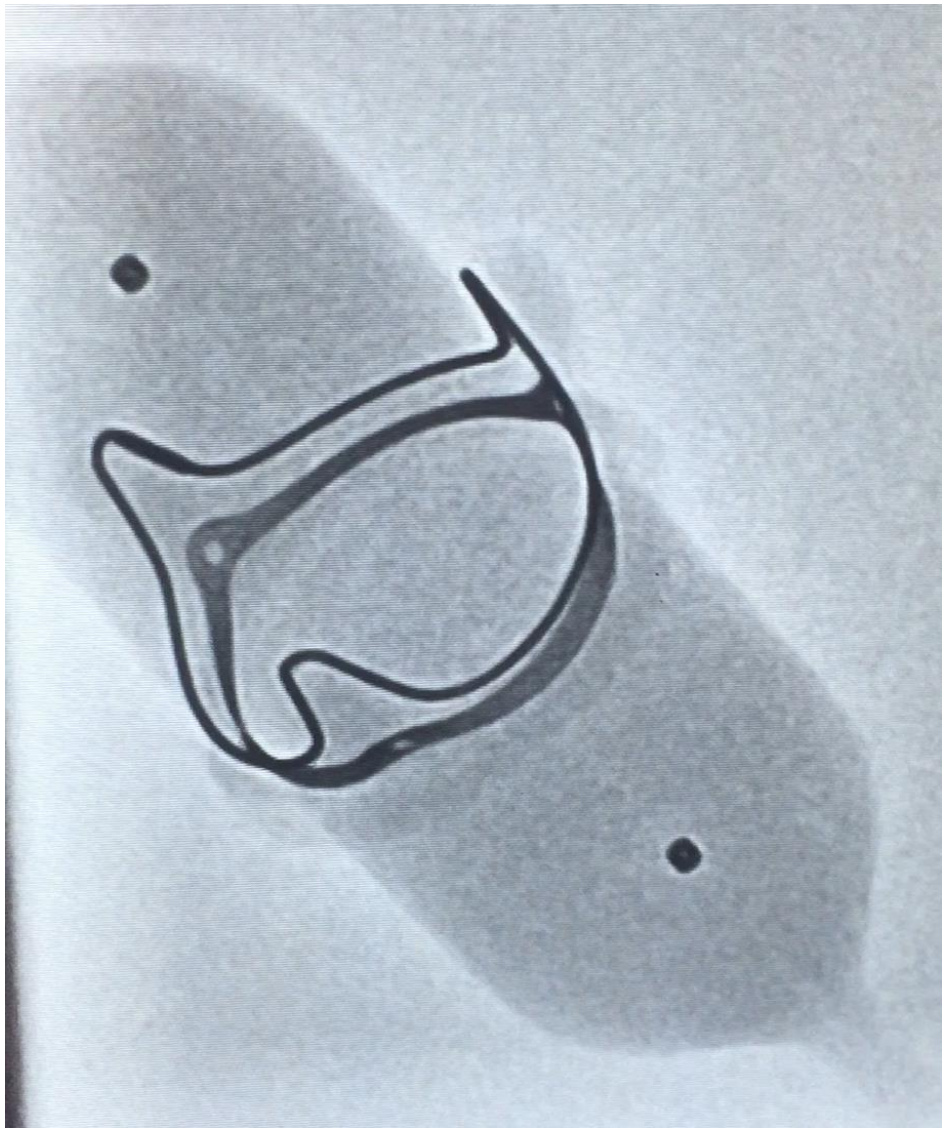
Medtronic supported this retrospective physician-initiated research by providing access to TVT Registry data and conducting the statistical analysis and is intended to inform the scientific community and it should not be viewed as promotional. The views or opinions presented here do not represent those of the American College of Cardiology (ACC) Foundation, the Society of Thoracic Surgeons (STS), the STS/ACC Transcatheter Valve Therapy (TVT) Registry or Medtronic. The industry data file upon which the analysis was performed is a subset of the full STS/ACC TVT Registry™ data submissions and the authors had full control of the analysis, presentation and subsequent publications.

Faculty disclosure information can be found on the app.

Background

BVF during VIV TAVR optimizes expansion of the transcatheter heart valve and minimizes residual gradients[1,2] with durable results reported out to 1-year[3]

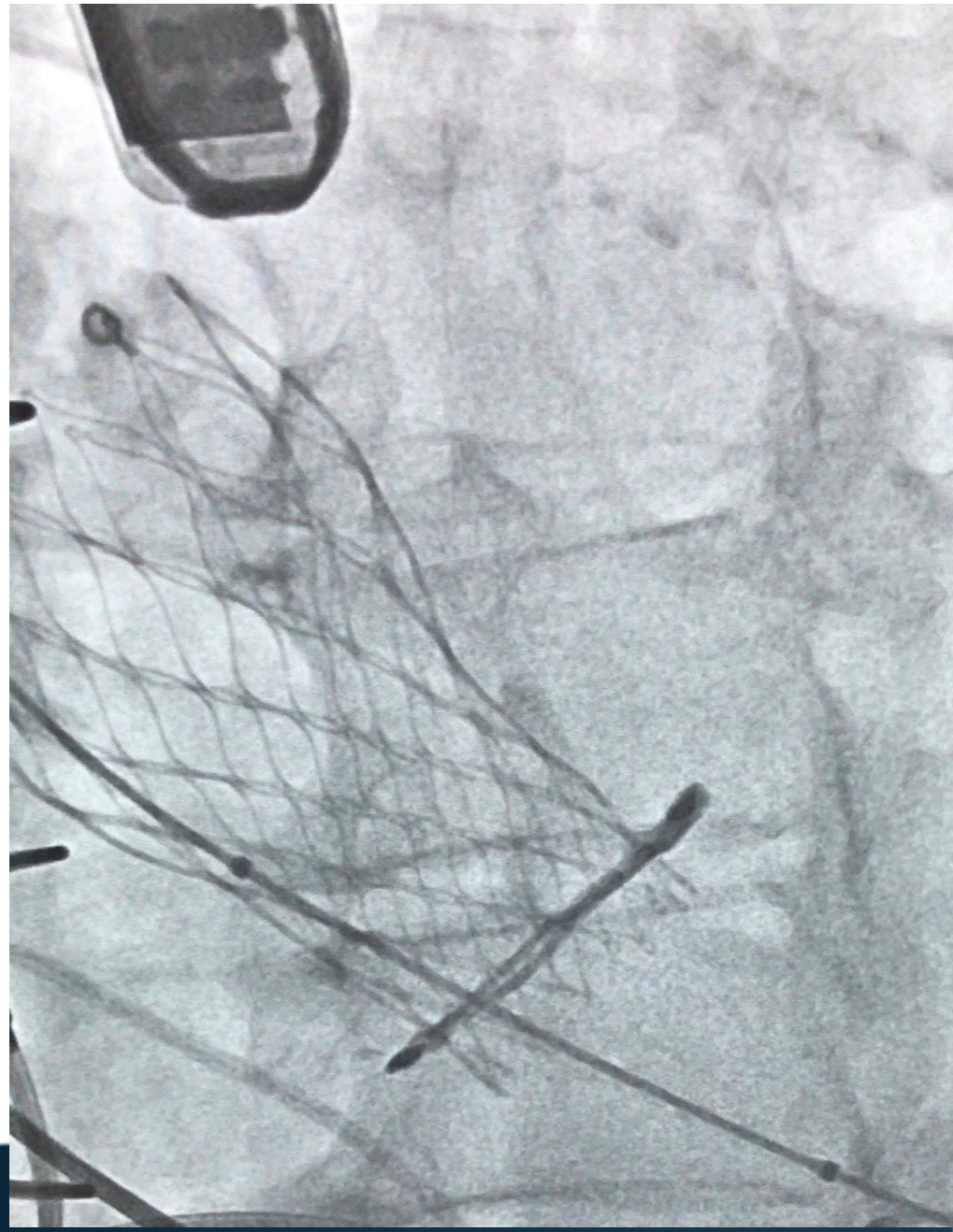
- The timing of BVF, whether performed before or after VIV TAVR, may impact outcomes[3,4]
- In a prior study, BVF performed *prior to VIV TAVR* with a balloon expandable valve was associated with higher rates of in-hospital mortality[5]
- We previously reported safety outcomes through 30 days with BVF using an Evolut THV[6]



1. Allen KB, Chhatriwalla A, et al. Ann Thorac Surg 2017;104:1501–8. 2. Allen KB, Chhatriwalla A, et al. JTCVS 2019;158(5):1317–1328.e1.
3. Chhatriwalla AK, Allen KB, Structural Heart 2021;5(4):433–435. 4. Meier D, et al. EuroIntervention. 2023;18(14):1165-1177. 5. Chhatriwalla AK, et al. JACC Cardiovasc Interv. 2023;16(5):530-539. 6. Allen KB and Chhatriwalla K. Presented at the American College of Cardiology annual meeting; March 4-6, 2023; New Orleans, LA.

Objective

To report the safety ***and*** echocardiographic outcomes in an expanded cohort of patients from the TVT Registry who underwent attempted BVF during VIV TAVR with an Evolut THV.



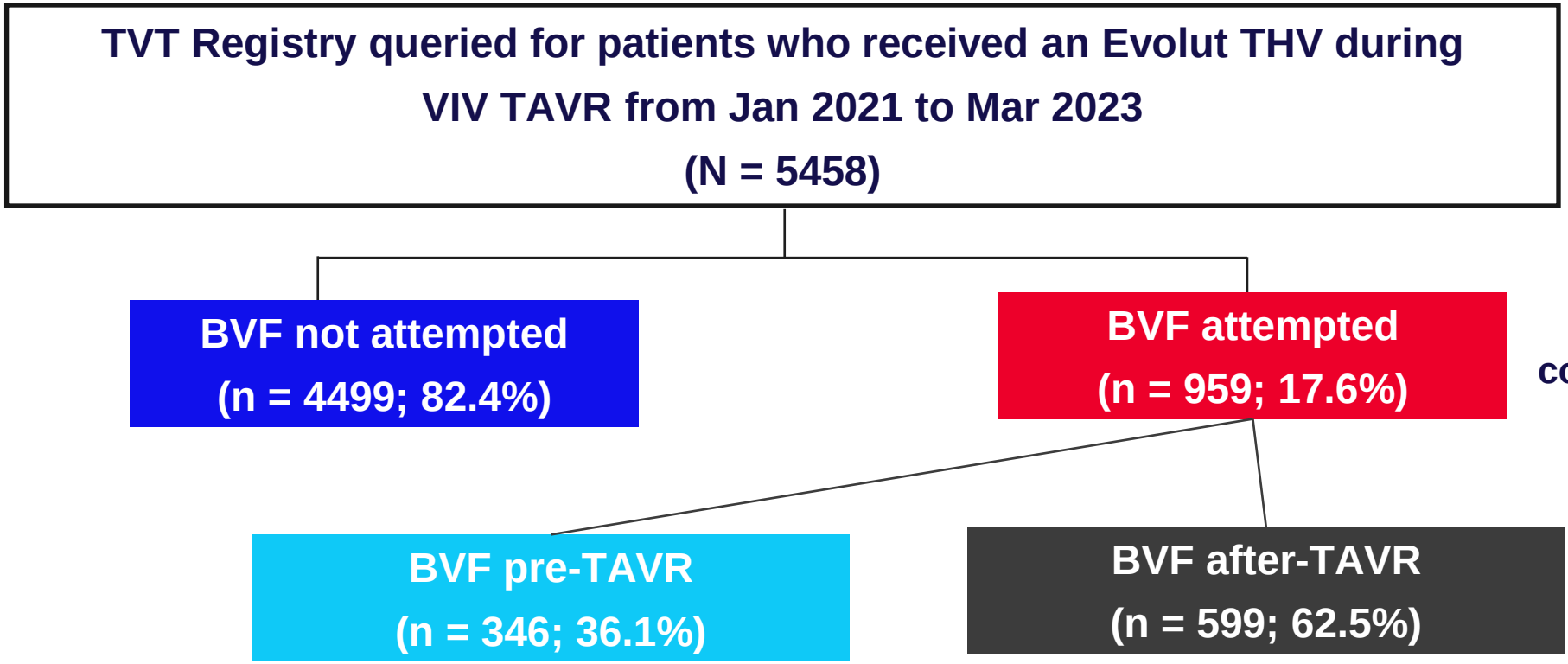
Statistical methods

- Safety outcomes were compared using inverse probability of treatment weighting (IPTW) to adjust for confounders, including demographic and clinical characteristics, and reported using logistic regression and Cox proportional-hazards models

- Echocardiographic outcomes were calculated using a generalized linear model to adjust for potential baseline confounders*, with separate models for each time point.

*Potential confounders included baseline mean gradient, baseline effective orifice area, body mass index, and sex.

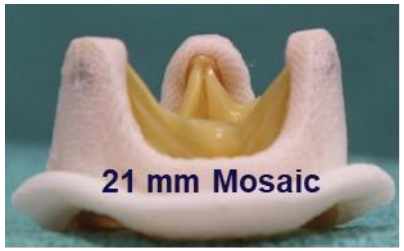
Methods - safety



Safety outcomes

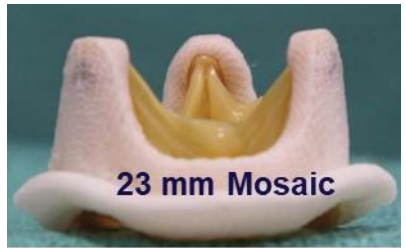
- In-hospital and 1-year adverse events

Methods - echocardiographic outcomes*



True Internal Diameter
17 mm

Echocardiographic outcomes through 30 days were evaluated in a subset of patients with small 21 mm and 23 mm Medtronic Mosaic surgical valves (N = 372)



True Internal Diameter
19 mm

BVF not attempted (n = 253; 68.0%)

BVF attempted (n = 119; 32.0%)

Echocardiographic outcomes

- Aortic valve area and mean gradient across the aortic valve

*The TVT Registry data sharing agreement only allows industry access to their own data. Therefore, only Medtronic surgical valves could be included for identification of true internal diameter.

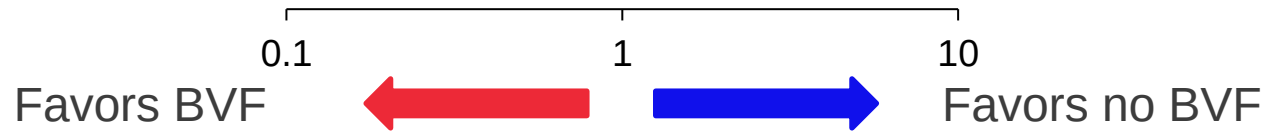
Baseline characteristics - BVF attempted vs BVF not attempted

	After IPTW adjustment		
Baseline characteristics, mean ± SD or %	**BVF attempted (n=959)**	**BVF not attempted (n=4499)**	**Absolute SMD**
Age, years	76.1	76.1	0.001
Male	55.0%	54.8%	0.003
NYHA Class III/IV	72.3%	72.5%	0.005
Diabetes mellitus	37.1%	37.2%	0.003
History of hypertension	94.2%	94.2%	0.003
Chronic lung disease/COPD	29.9%	29.9%	0.001
CABG	38.2%	37.9%	0.005
History of PCI	24.1%	24.0%	0.004
Pre-existing IPG/ICD	16.4%	16.4%	0.001
Atrial fibrillation/ atrial flutter	45.3%	45.0%	0.005
Cardiogenic shock w/in 24hr	1.1%	1.2%	0.002
Mean gradient, mmHg	41.2	41.2	0.007
Aortic valve area, cm^2	0.8	0.8	0.023
Moderate/severe AR	34.7%	34.9%	0.005
SAV type MDT	19.3%	19.1%	0.007

After IPTW adjustment baseline characteristics were well balanced

In-hospital adverse events – BVF attempted vs BVF not attempted

	BVF attempted (n = 959)	BVF not attempted (n = 4499)	Odds ratio (95% CI)	*P* value
All-cause mortality	0.94%	1.38%	0.68 (0.33, 1.38)	0.29
Cardiovascular mortality	0.73%	1.07%	0.68 (0.31, 1.52)	0.35
Any stroke	1.46%	2.12%	0.69 (0.39, 1.22)	0.20
Bleeding*	5.42%	5.44%	1.00 (0.73, 1.37)	0.98
Coronary compression	0.10%	0.29%	0.36 (0.05, 2.82)	0.33
New pacemaker†	3.87%	3.12%	1.25 (0.82, 1.90)	0.30
Cardiac arrest	2.92%	2.67%	1.10 (0.72, 1.68)	0.68
Device migration	0.52%	0.20%	2.62 (0.84, 8.11)	0.10

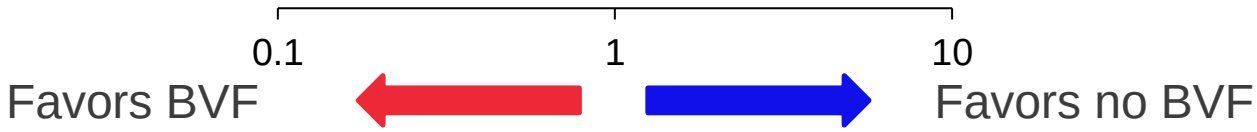


There were no differences in the rates of in-hospital adverse events Between BVF attempted vs BVF not attempted

Inverse probability of treatment weighting adjusted analysis. Adverse event rates reported as proportion of patients with an event. P values are from a logistic model.
*Major or life threatening. †Excludes pacemaker at baseline. BVF, bioprosthetic valve fracture.

1-year adverse events – BVF attempted vs BVF not attempted

	BVF attempted (n = 959)	BVF not attempted (n = 4499)	Hazard ratio (95% CI)	*P* value
All-cause mortality	8.33%	9.03%	0.87 (0.64, 1.20)	0.41
Cardiovascular mortality	2.57%	3.63%	0.68 (0.40, 1.15)	0.15
Any stroke	2.17%	4.22%	0.57 (0.35, 0.94)	0.028
Myocardial infarction	0.69%	1.30%	0.41 (0.12, 1.34)	0.14
Vascular complication	5.24%	6.04%	0.87 (0.64, 1.19)	0.39
New pacemaker*	7.07%	5.54%	1.26 (0.90, 1.77)	0.17
Aortic-valve reintervention	0.85%	1.15%	0.75 (0.31, 1.79)	0.52
Percutaneous coronary intervention	1.07%	1.57%	0.76 (0.37, 1.57)	0.46
Valve-related readmission	3.41%	1.79%	1.83 (1.06, 3.15)	0.029



Inverse probability of treatment weighting adjusted analysis. Adverse event rates reported as Kaplan-Meier estimates. *P* value are from Cox model. *Excludes pacemaker at baseline. BVF, bioprosthetic valve fracture.

1-year adverse events – BVF attempted vs BVF not attempted

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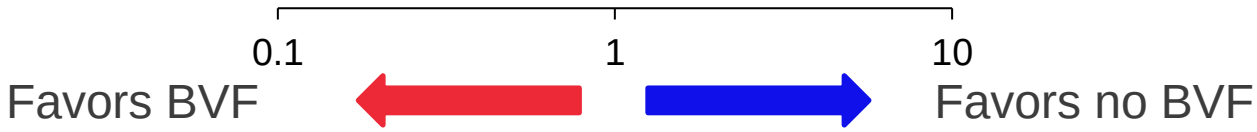


The rate of stroke was lower and the rate of valve-related readmissions was higher with attempted BVF.

Baseline characteristics - BVF timing

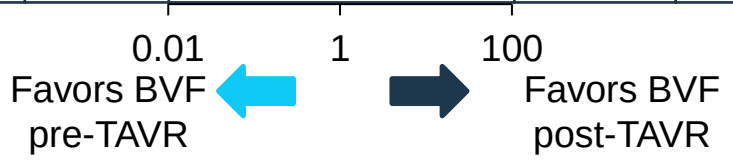
Baseline characteristics, mean ± SD or %	After IPTW adjustment		
	BVF pre-TAVR (n = 346)	BVF post-TAVR (n = 599)	Absolute SMD
Age, years	76.0	75.7	0.031
Male	53.8%	54.1%	0.011
NYHA Class III/IV	70.4%	69.7%	0.019
Diabetes mellitus	36.1%	36.1%	0.004
History of hypertension	94.5%	94.9%	0.023
Chronic lung disease/COPD	31.5%	30.5%	0.024
CABG	39.9%	39.6%	0.009
History of PCI	23.4%	22.8%	0.017
Pre-existing IPG/ICD	16.8%	16.6%	0.007
Atrial fibrillation/ atrial flutter	44.5%	42.9%	0.036
Cardiogenic shock w/in 24hr	2.0%	1.6%	0.041
Mean gradient, mmHg	40.6	40.7	0.008
Aortic valve area, cm^2	0.8	0.8	0.024
Moderate/severe AR	34.1%	34.1%	0.009
SAV type MDT	20.8%	20.5%	0.011

After IPTW adjustment baseline characteristics were well balanced

Safety outcomes – BVF timing

In-hospital adverse events

	BVF pre-TAVR (n = 346)	BVF post-TAVR (n = 599)	Odds ratio (95% CI)	*P* value
All-cause mortality	0.87%	0.63%	1.37 (0.34, 5.60)	0.66
Cardiovascular mortality	0.87%	0.40%	2.19 (0.48, 10.10)	0.31
Any stroke	1.16%	1.92%	0.60 (0.17, 2.11)	0.42
Bleeding*	4.91%	4.97%	0.99 (0.52, 1.86)	0.97
Coronary compression	0.00%	0.10%	NA	NA
New pacemaker†	4.86%	3.04%	1.63 (0.76, 3.50)	0.21
Cardiac arrest	4.62%	1.96%	2.42 (1.07, 5.49)	0.03
Device migration	0.29%	0.52%	0.56 (0.06, 5.15)	0.61



Inverse probability of treatment weighting adjusted analysis. In-hospital adverse event rates reported as proportion of patients with an event and 1-year adverse event rates are reported as Kaplan-Meier estimates. P values are from a logistic model for in-hospital events and from Cox models for 1-year events. *Major or life threatening. †Excludes pacemaker at baseline. BVF, bioprosthetic valve fracture; MI, myocardial infarction.

Safety outcomes – BVF timing

In-hospital adverse events

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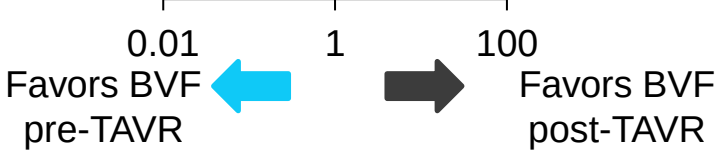
Any stroke	1.16%	1.92%	0.60 (0.17, 2.11)	0.42
Bleeding*	4.91%	4.97%	0.99 (0.52, 1.86)	0.97
Coronary compression	0.00%	0.10%	NA	NA
New pacemaker†	4.86%	3.04%	1.63 (0.76, 3.50)	0.21
Cardiac arrest	4.62%	1.96%	2.42 (1.07, 5.49)	0.03
Device migration	0.29%	0.52%	0.56 (0.06, 5.15)	0.61



1-year adverse events

	BVF pre-TAVR (n = 346)	BVF post-TAVR (n = 599)	Hazard ratio (95% CI)	*P* value
All-cause mortality	8.25%	7.98%	0.91 (0.48, 1.73)	0.77
Cardiovascular mortality	1.54%	2.70%	0.71 (0.22, 2.28)	0.57
Any stroke	1.84%	2.53%	0.60 (0.20, 1.81)	0.37
MI	0.62%	0.46%	1.38 (0.11, 16.83)	0.80
Vascular complication	5.77%	4.74%	1.11 (0.60, 2.04)	0.75
New pacemaker†	8.25%	7.13%	1.16 (0.61, 2.19)	0.65
Aortic-valve reintervention	0.30%	0.92%	0.43 (0.05, 3.92)	0.46
Percutaneous coronary intervention	1.51%	0.55%	2.11 (0.55, 8.12)	0.28
Valve-related readmission	2.48%	4.10%	0.81 (0.30, 2.20)	0.68

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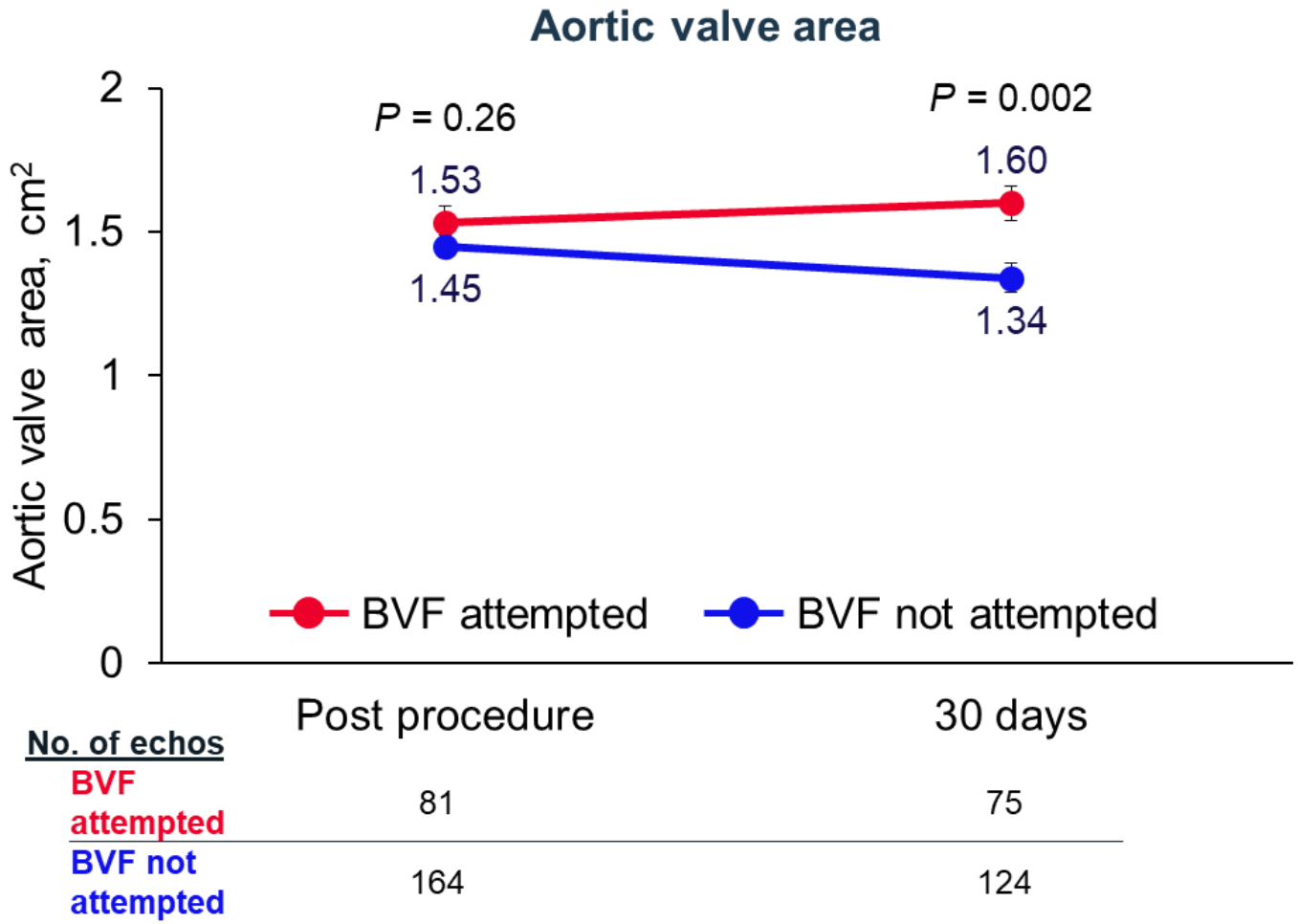
Inverse probability of treatment weighting adjusted analysis. In-hospital adverse event rates reported as proportion of patients with an event and 1-year adverse event rates are reported as Kaplan-Meier estimates. P values are from a logistic model for in-hospital events and from Cox models for 1-year events. *Major or life threatening. †Excludes pacemaker at baseline. BVF, bioprosthetic valve fracture; MI, myocardial infarction.

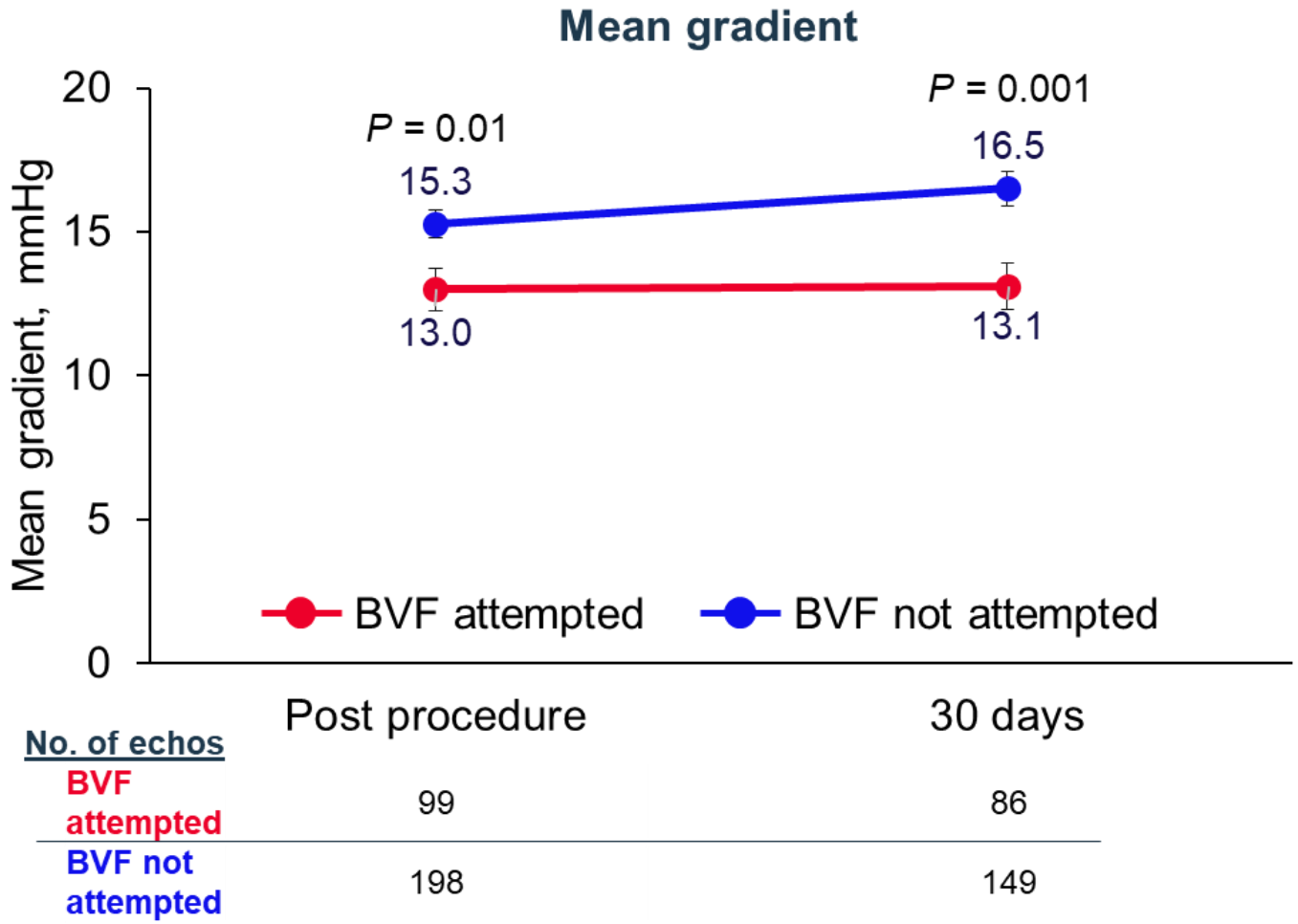
Echocardiographic outcomes
BVF attempted vs BVF not attempted
(21 mm and 23 mm Medtronic Mosaic valves)



No. of echos	Post procedure	30 days
BVF attempted	81	75
BVF not attempted	164	124

Values are reported as Least-Square Means ± SE. Statistics were calculated using a generalized linear model to adjust for baseline mean gradient, baseline effective orifice area, body mass index, and sex, with separate models for each time point. BVF, bioprosthetic valve fracture; SAV, surgical aortic valve.

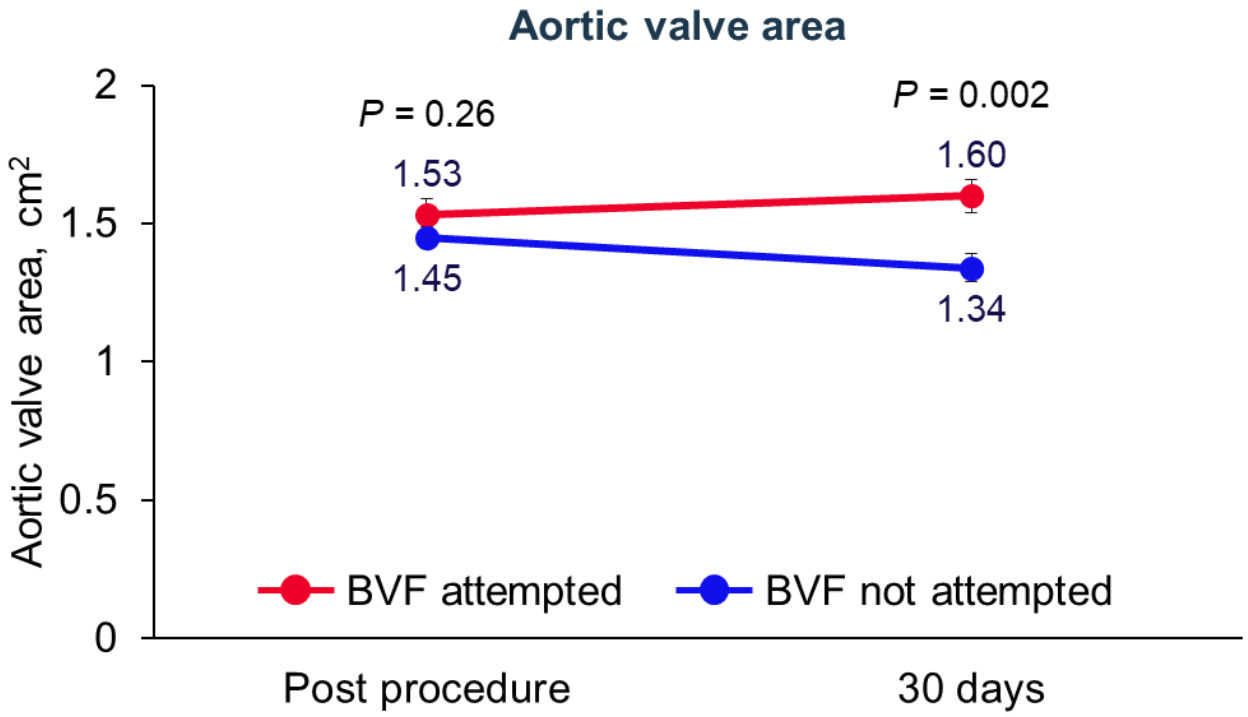
Echocardiographic outcomes
BVF attempted vs BVF not attempted
(21 mm and 23 mm Medtronic Mosaic valves)

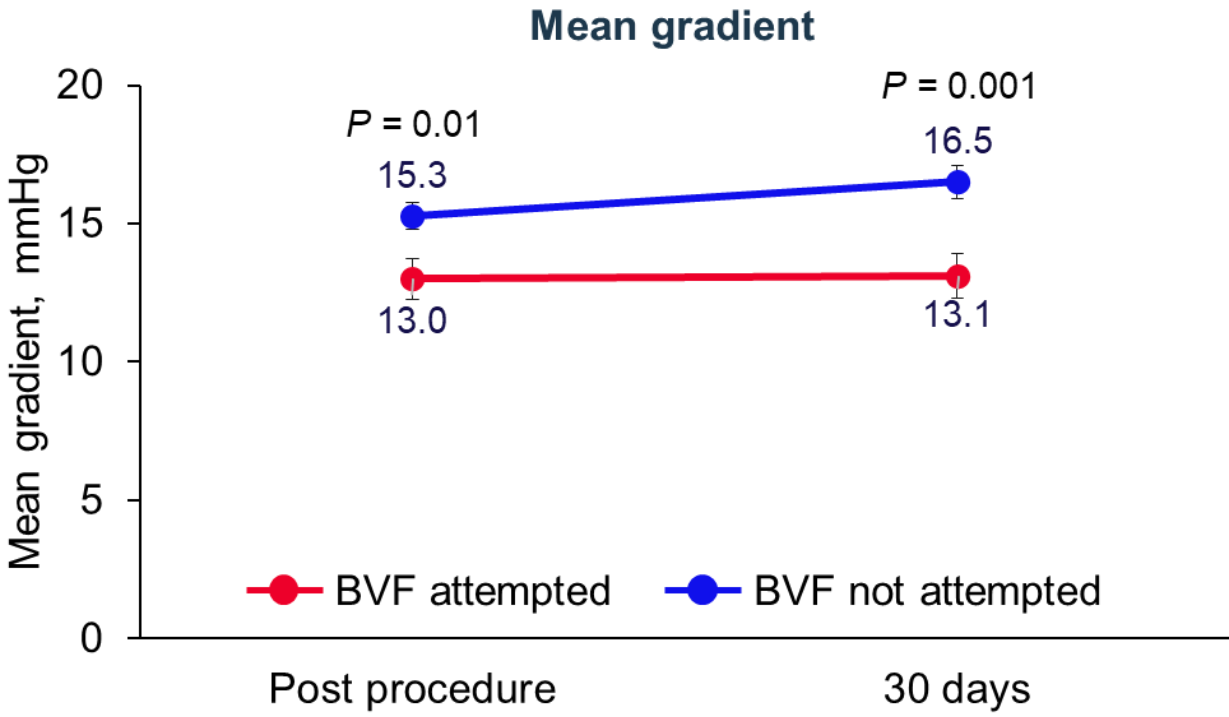


No. of echos	Post procedure	30 days
BVF attempted	99	86
BVF not attempted	198	149

Values are reported as Least-Square Means ± SE. Statistics were calculated using a generalized linear model to adjust for baseline mean gradient, baseline effective orifice area, body mass index, and sex, with separate models for each time point. BVF, bioprosthetic valve fracture; SAV, surgical aortic valve.

Echocardiographic outcomes
BVF attempted vs BVF not attempted
(21 mm and 23 mm Medtronic Mosaic valves)





At 30 days, attempted BVF resulted in a larger aortic valve area and a lower mean gradient

Limitations

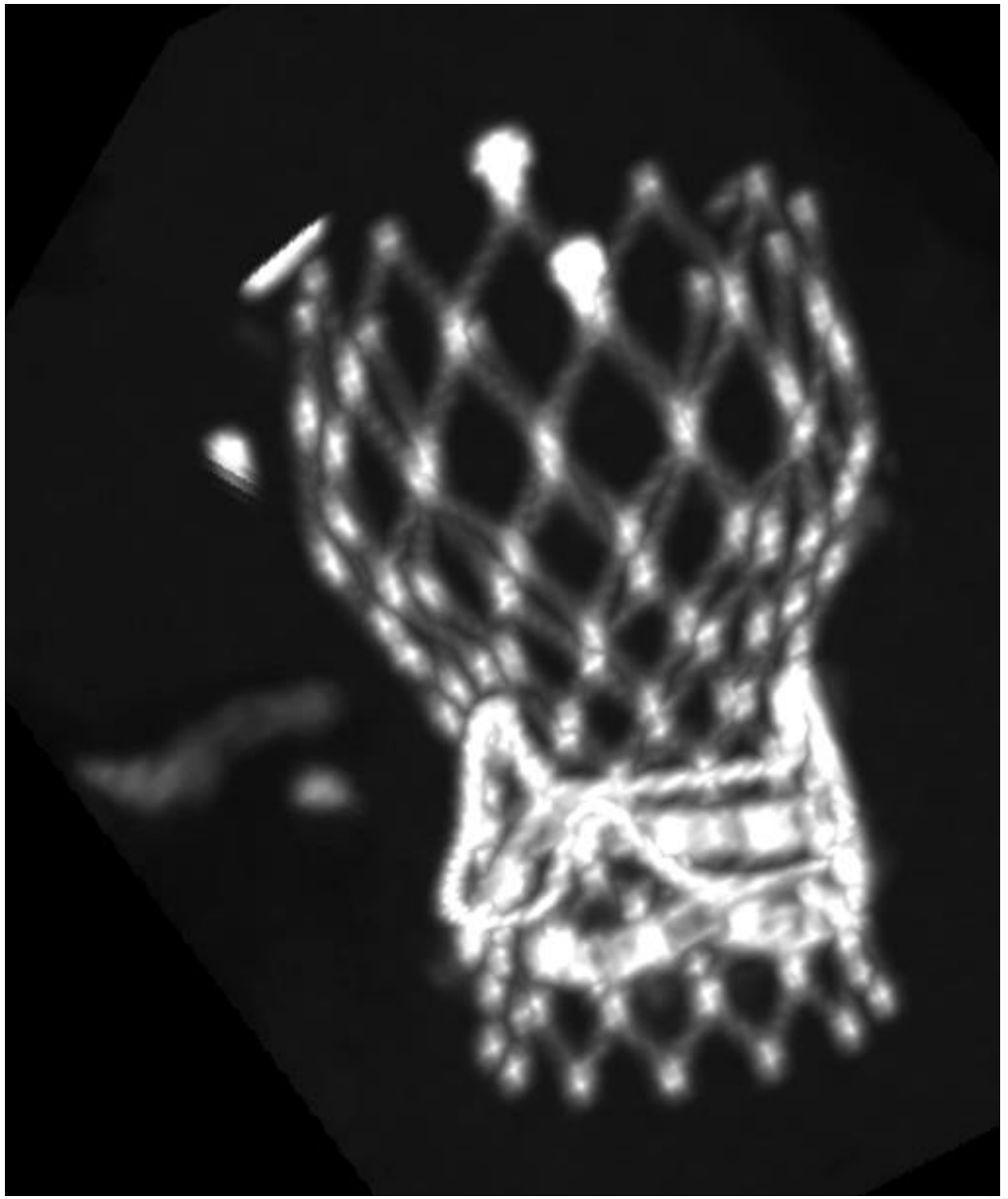
- TVT Registry reflects only attempted BVF and does not confirm that BVF actually occurred
- The rationale for patient selection for BVF can’t be obtained from the TVT
- Only baseline and final echo parameters are provided by the TVT Registry, however, the reduction in interim gradients and improvement in AVA have been previously reported[1,2]
- Findings from the echocardiography subgroup analysis apply only to Medtronic Mosaic surgical valves

1. Chhatriwalla AK, Allen KB, et al. Circ Cardiovasc Interv 2024 Jul;17(7):e014276. 2. Allen KB, Chhatriwalla A, et al. JTCVS 2019;158(5):1317–1328.e1.

Conclusions

In patients undergoing VIV TAVR with an Evolut, BVF attempted compared to BVF not attempted

- Was safer when performed ***after*** VIV TAVR
- Resulted in a larger aortic valve area and a lower mean gradient at 30 days in patients with small Mosaic surgical valves
- Was associated with a lower rate of stroke but a higher rate of valve-related readmissions at 1-year
- More research is needed on the long-term effects of BVF on patient outcomes and valve durability



THANK YOU