International BASILICA and CHIMNEY Registry Results

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Disclosures

- Advisory boards: Abbott Vascular, Amgen, Boston Scientific, Medtronic, Philips Volcano, Pi-Cardia LTD, and Cardioset
- Consultant: Abbott Vascular, Amgen, Biosensors, Biotronik, Boston Scientific, Medtronic, Philips Volcano
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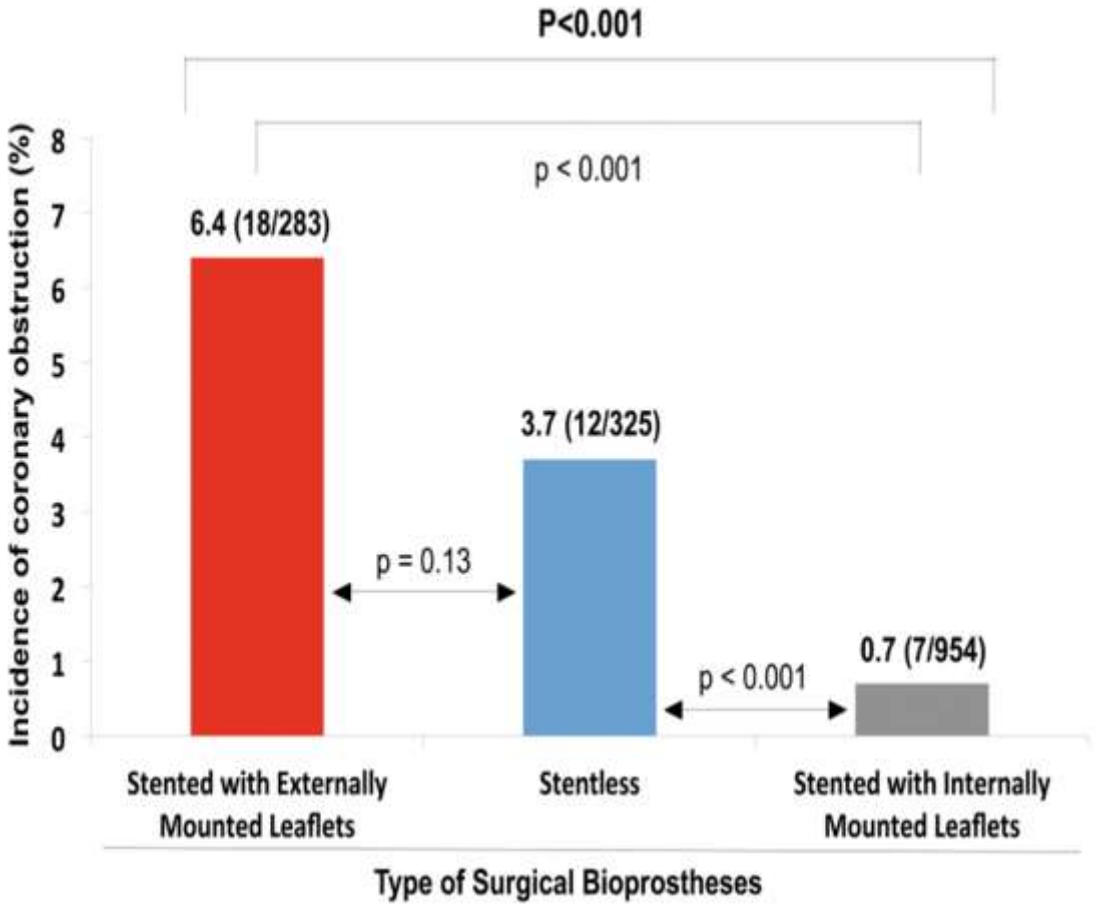
- Speaker bureau: AstraZeneca, and Chiesi
- Equity: MedAlliance, DOMed, Pi-Cardia LTD, Cardioset

Background and Objectives

- TAVR causes coronary artery obstruction in 0.7% of cases, with 40-50% mortality
- Snorkel and Stenting (chimney) has been used as the default to prevent coronary obstruction during TAVR procedure
- BASILICA is a novel technique to lacerate aortic leaflets to prevent TAVR-related coronary artery obstruction
- There are little data on predicting coronary obstruction risk in patients with native aortic stenosis
- Given the low prevalence *but high mortality*, who should undergo a protection strategy?
- What should be the preferred method to protect the coronaries during TAVR

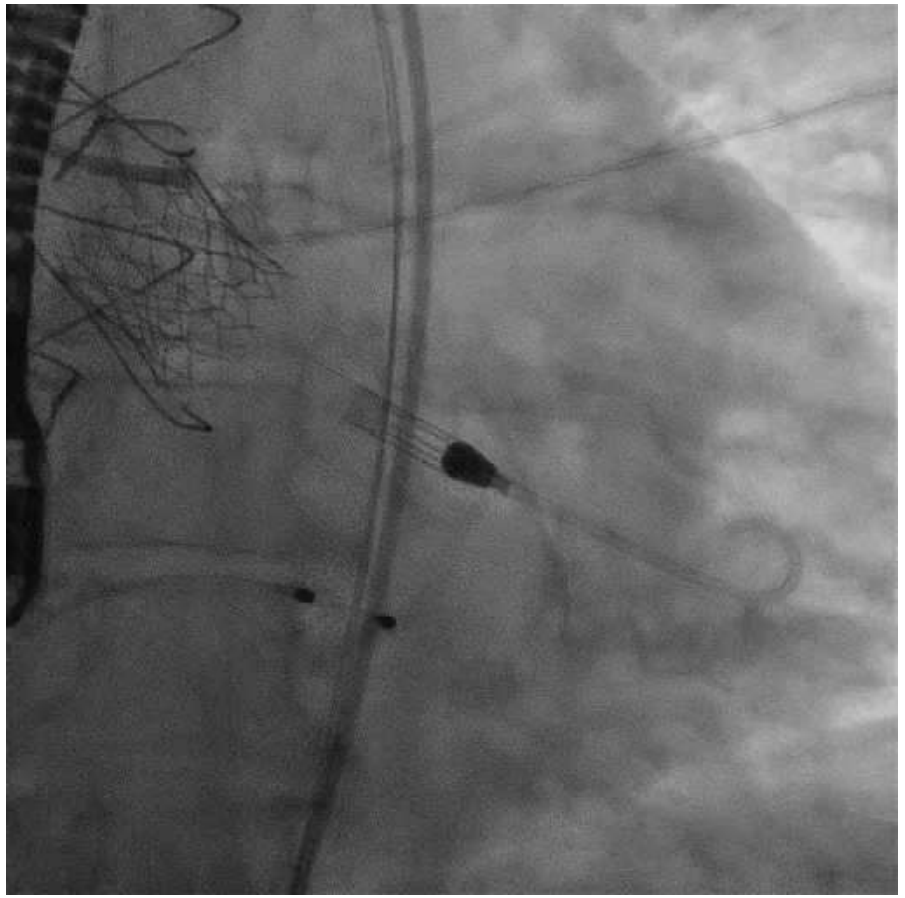
Incidence of Coronary Obstruction in Surgical Valves



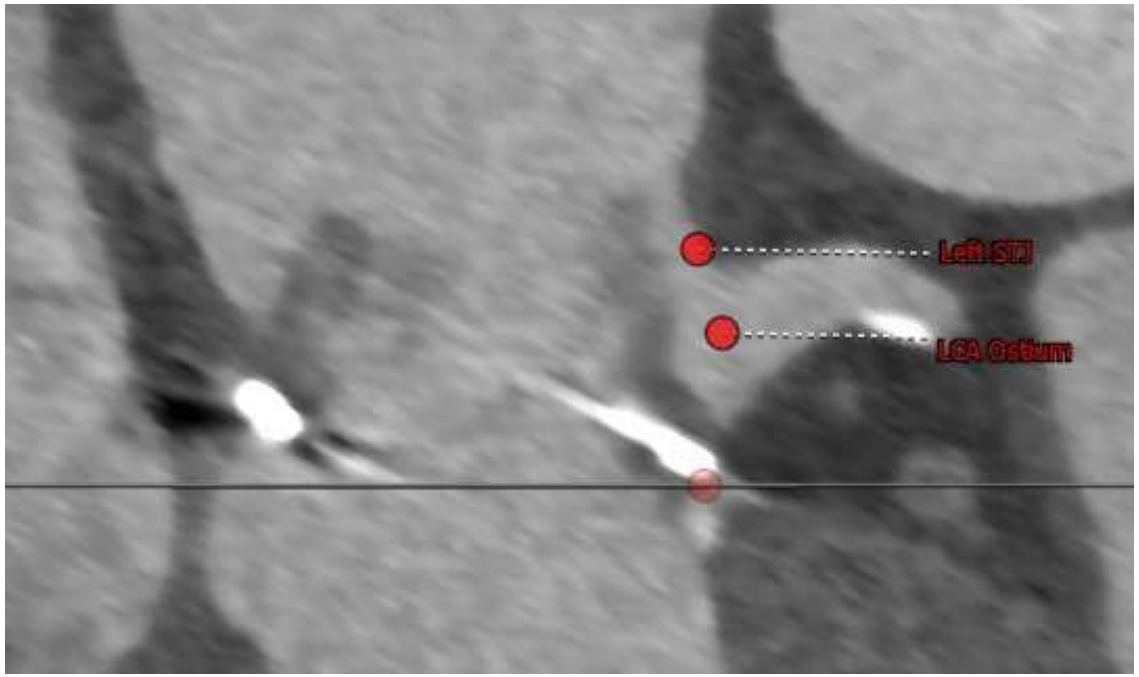
bioprosthetic surgical valves: insights from the VIVID registry, European Heart Journal, Volume 39, Issue 8, 21 February 2018, Pages 687–695,

Background

- Coronary obstruction is a rare but morbid complication of TAVR



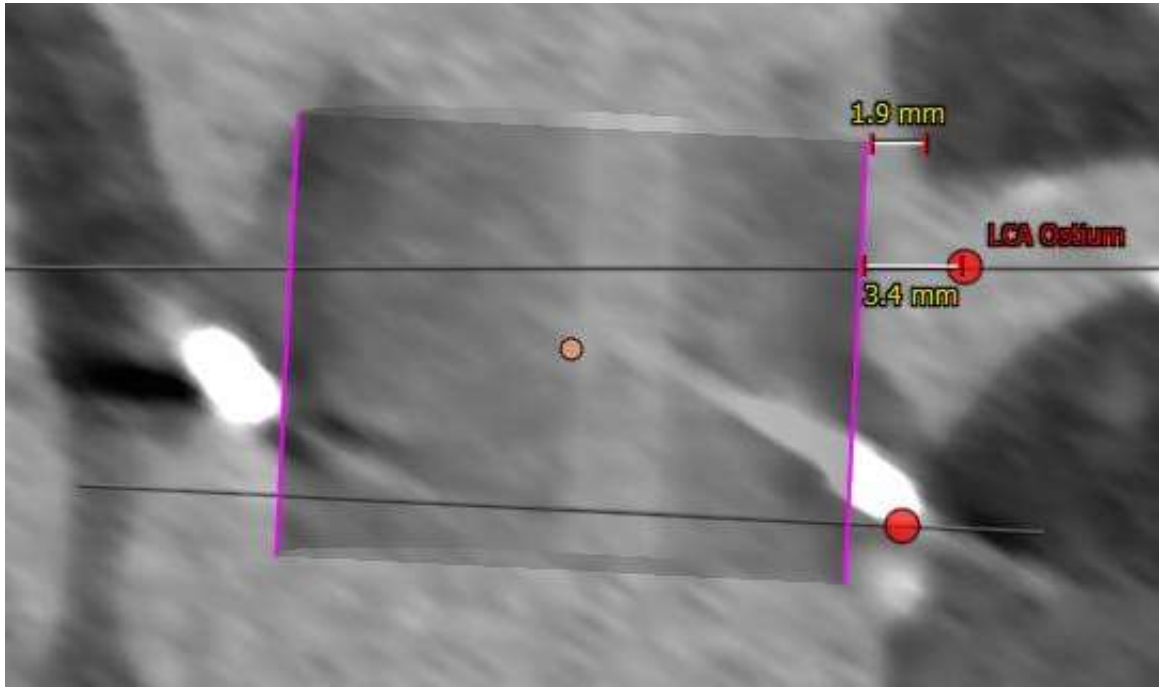
- Anatomic Risk Factors for coronary obstruction
  - Low Coronary Height
  - Narrow Sinus of Valsalva Diameters



Ribeiro, H. B, et al. (2013). "Predictive Factors, Management, and Clinical Outcomes of Coronary Obstruction Following Transcatheter Aortic Valve Implantation Insights From a Large Multicenter Registry." Journal of the American College of Cardiology 62(17): 1552-1562.

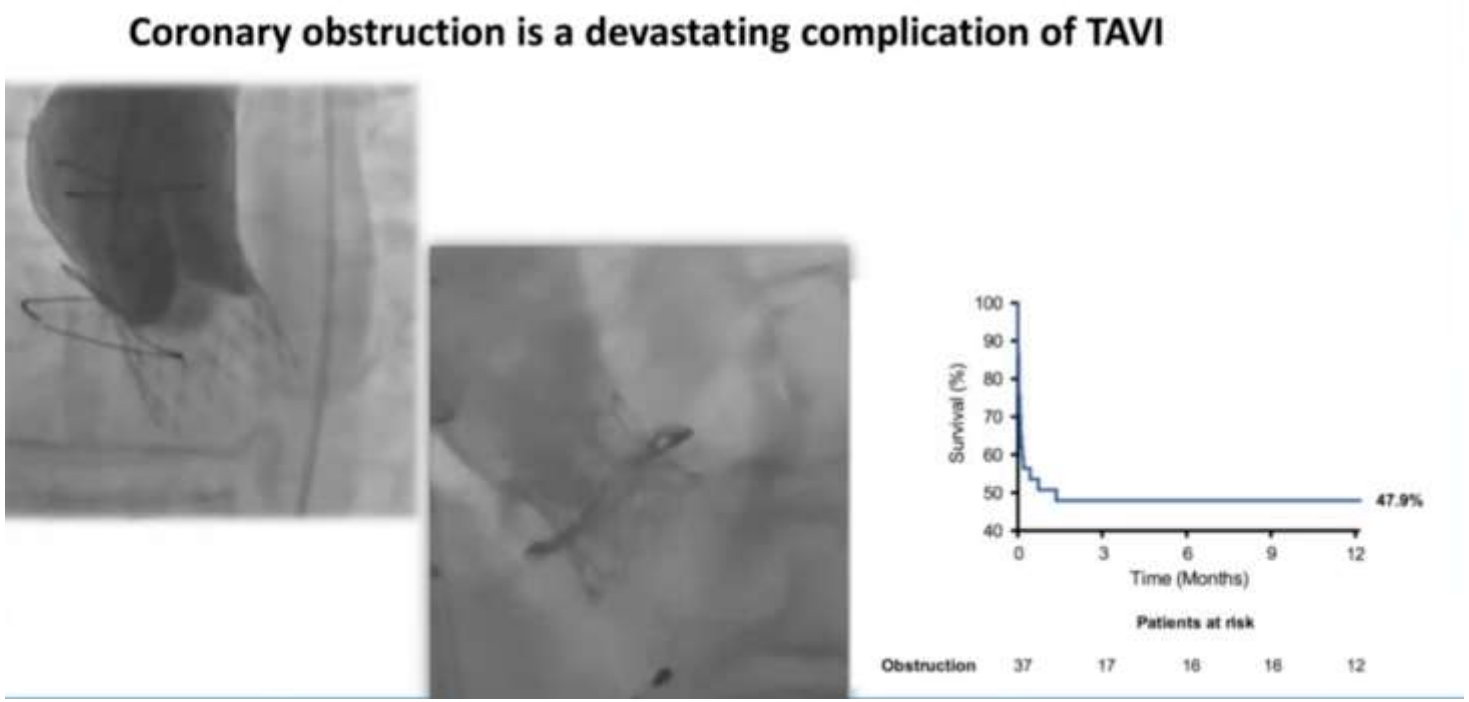
Novel Predictors

- CT Analysis
  - Virtual Valve-to-Coronary Distance
  - Virtual Valve-to-STJ Distance
  - Leaflet height relative to coronary ostium



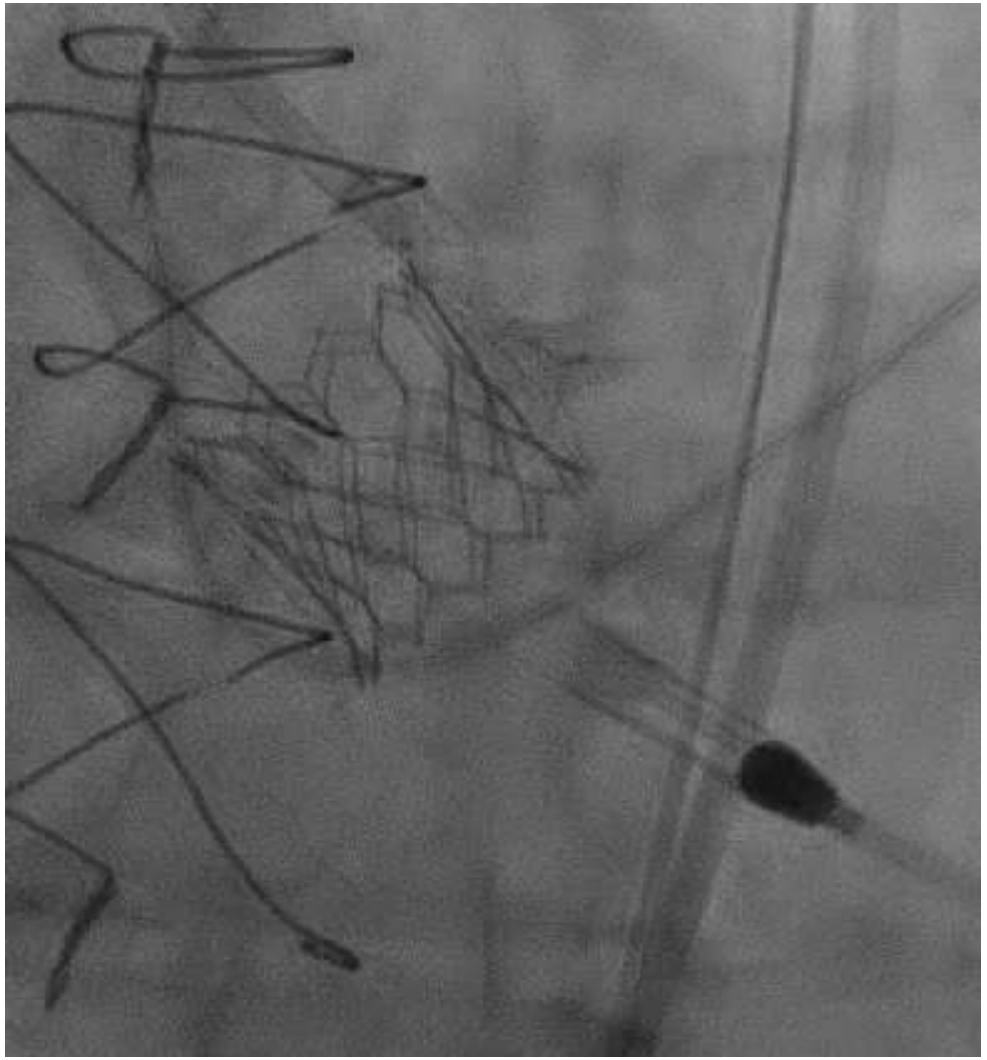
Methods to prevent coronary obstruction post TAVR

- Snorkel Stenting + TAVR
- BASILICA + TAVR
- Surgery



Snorkel Stenting

- <u>Advantages</u>
  - Operator familiarity
  - Preventive or therapeutic measure
- <u>Limitations</u>
  - Risk of stent compression
  - Difficult/Impossible to traverse pinned leaflets
  - Often performed emergently
  - Need for lifelong DAPT
  - Turbulent blood flow



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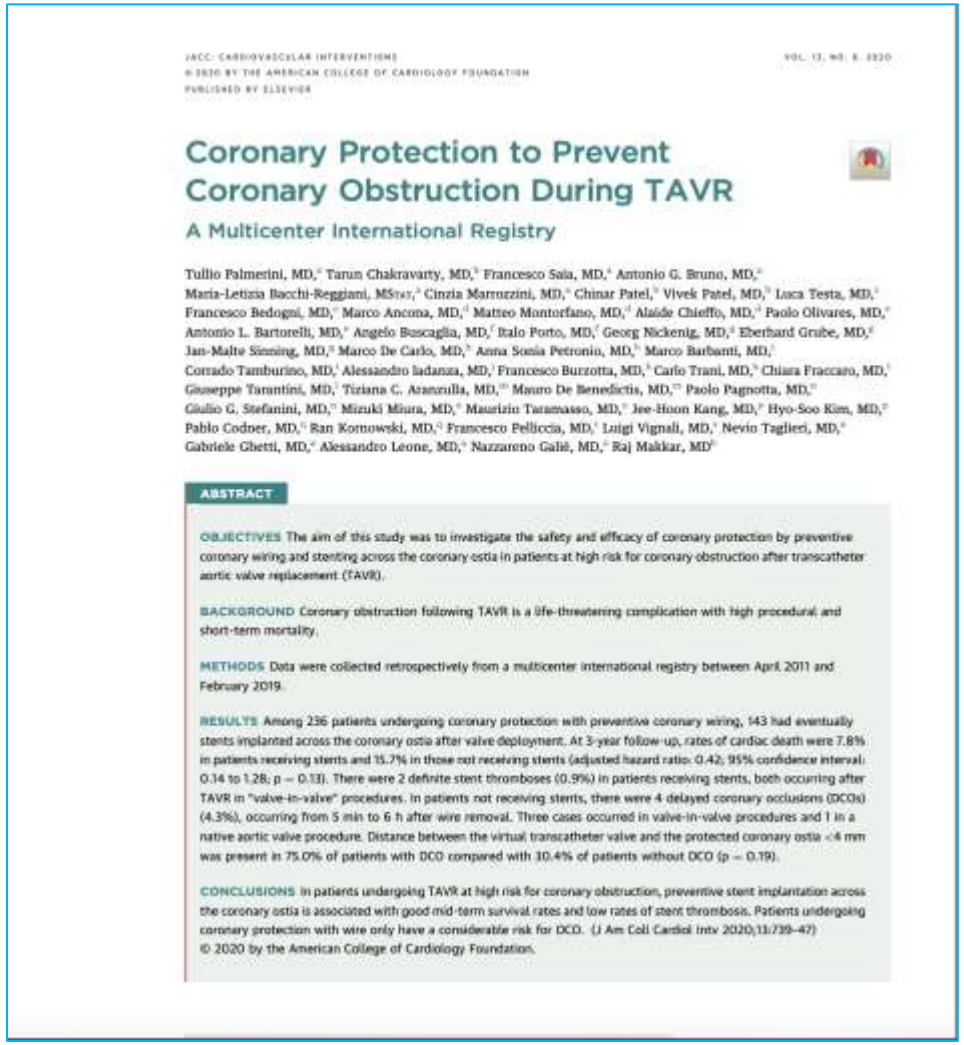
Coronary Protection with Snorkel and Stenting in the Literature



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Coronary Protection to Prevent Coronary Obstruction During TAVR

A Multicenter International Registry

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ABSTRACT

OBJECTIVES The aim of this study was to investigate the safety and efficacy of coronary protection by preventive coronary wiring and stenting across the coronary ostia in patients at high risk for coronary obstruction after transcatheter aortic valve replacement (TAVR).

BACKGROUND Coronary obstruction following TAVR is a life-threatening complication with high procedural and short-term mortality.

METHODS Data were collected retrospectively from a multicenter international registry between April 2011 and February 2019.

RESULTS Among 236 patients undergoing coronary protection with preventive coronary wiring, 143 had eventually stents implanted across the coronary ostia after valve deployment. At 3-year follow-up, rates of cardiac death were 7.8% in patients receiving stents and 15.7% in those not receiving stents (adjusted hazard ratio: 0.42; 95% confidence interval: 0.14 to 1.28; p = 0.13). There were 2 definite stent thromboses (0.9%) in patients receiving stents, both occurring after TAVR in "valve-in-valve" procedures. In patients not receiving stents, there were 4 delayed coronary occlusions (DCOs) (4.3%), occurring from 5 min to 6 h after wire removal. Three cases occurred in valve-in-valve procedures and 1 in a native aortic valve procedure. Distance between the virtual transcatheter valve and the protected coronary ostia <4 mm was present in 75.0% of patients with DCO compared with 30.4% of patients without DCO (p = 0.19).

CONCLUSIONS In patients undergoing TAVR at high risk for coronary obstruction, preventive stent implantation across the coronary ostia is associated with good mid-term survival rates and low rates of stent thrombosis. Patients undergoing coronary protection with wire only have a considerable risk for DCO. (J Am Coll Cardiol Intv 2020;13:739–47)
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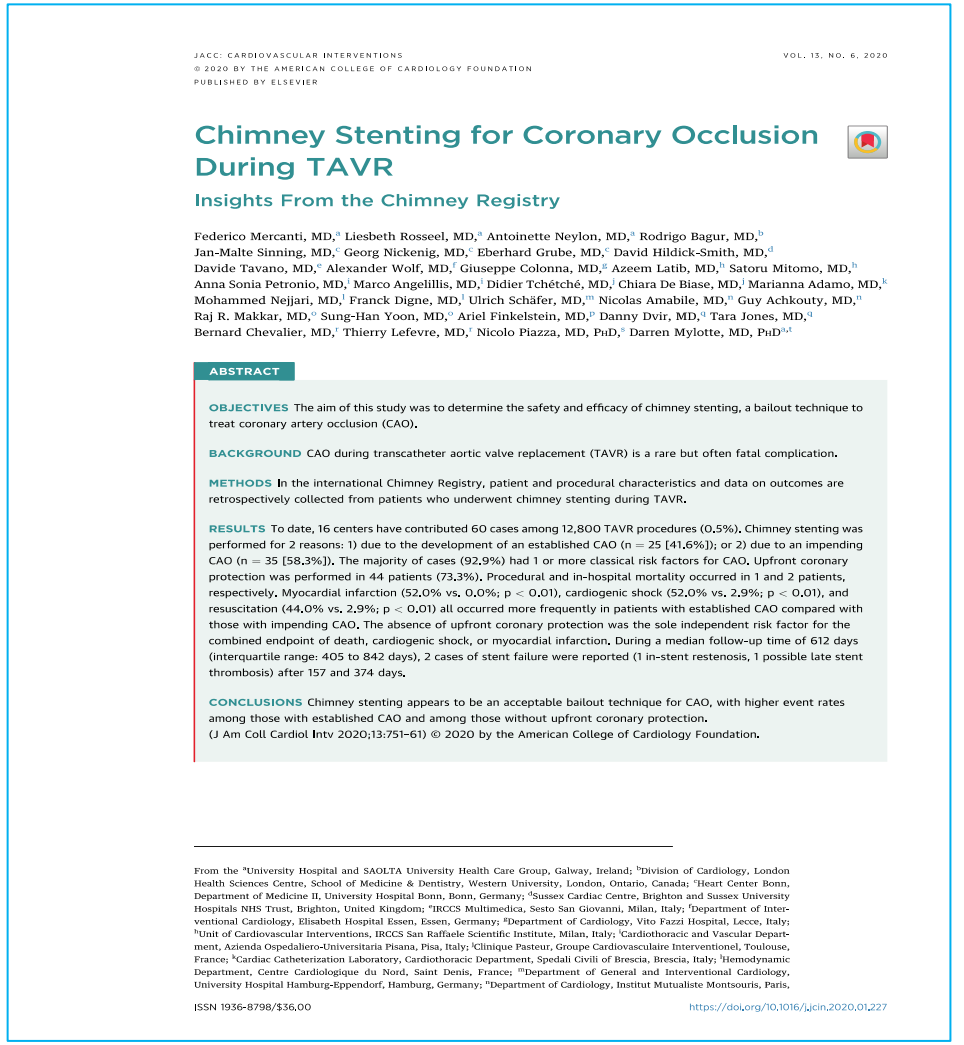

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Chimney Stenting for Coronary Occlusion During TAVR

Insights From the Chimney Registry

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ABSTRACT

OBJECTIVES The aim of this study was to determine the safety and efficacy of chimney stenting, a bailout technique to treat coronary artery occlusion (CAO).

BACKGROUND CAO during transcatheter aortic valve replacement (TAVR) is a rare but often fatal complication.

METHODS In the international Chimney Registry, patient and procedural characteristics and data on outcomes are retrospectively collected from patients who underwent chimney stenting during TAVR.

RESULTS To date, 16 centers have contributed 60 cases among 12,800 TAVR procedures (0.5%). Chimney stenting was performed for 2 reasons: 1) due to the development of an established CAO (n = 25 [41.6%]); or 2) due to an impending CAO (n = 35 [58.3%]). The majority of cases (92.9%) had 1 or more classical risk factors for CAO. Upfront coronary protection was performed in 44 patients (73.3%). Procedural and in-hospital mortality occurred in 1 and 2 patients, respectively. Myocardial infarction (52.0% vs. 0.0%; p < 0.01), cardiogenic shock (52.0% vs. 2.9%; p < 0.01), and resuscitation (44.0% vs. 2.9%; p < 0.01) all occurred more frequently in patients with established CAO compared with those with impending CAO. The absence of upfront coronary protection was the sole independent risk factor for the combined endpoint of death, cardiogenic shock, or myocardial infarction. During a median follow-up time of 612 days (interquartile range: 405 to 842 days), 2 cases of stent failure were reported (1 in-stent restenosis, 1 possible late stent thrombosis) after 157 and 374 days.

CONCLUSIONS Chimney stenting appears to be an acceptable bailout technique for CAO, with higher event rates among those with established CAO and among those without upfront coronary protection.
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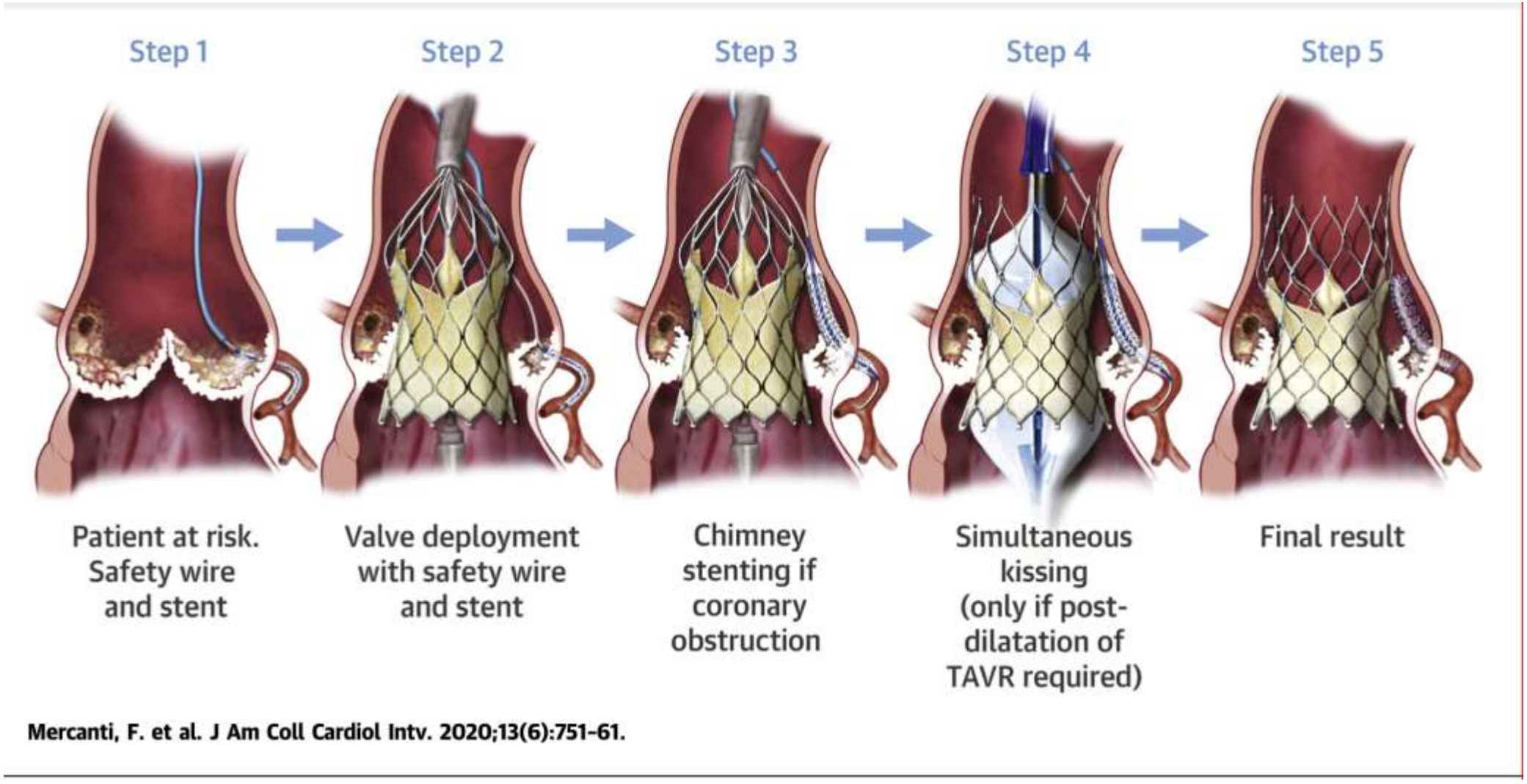
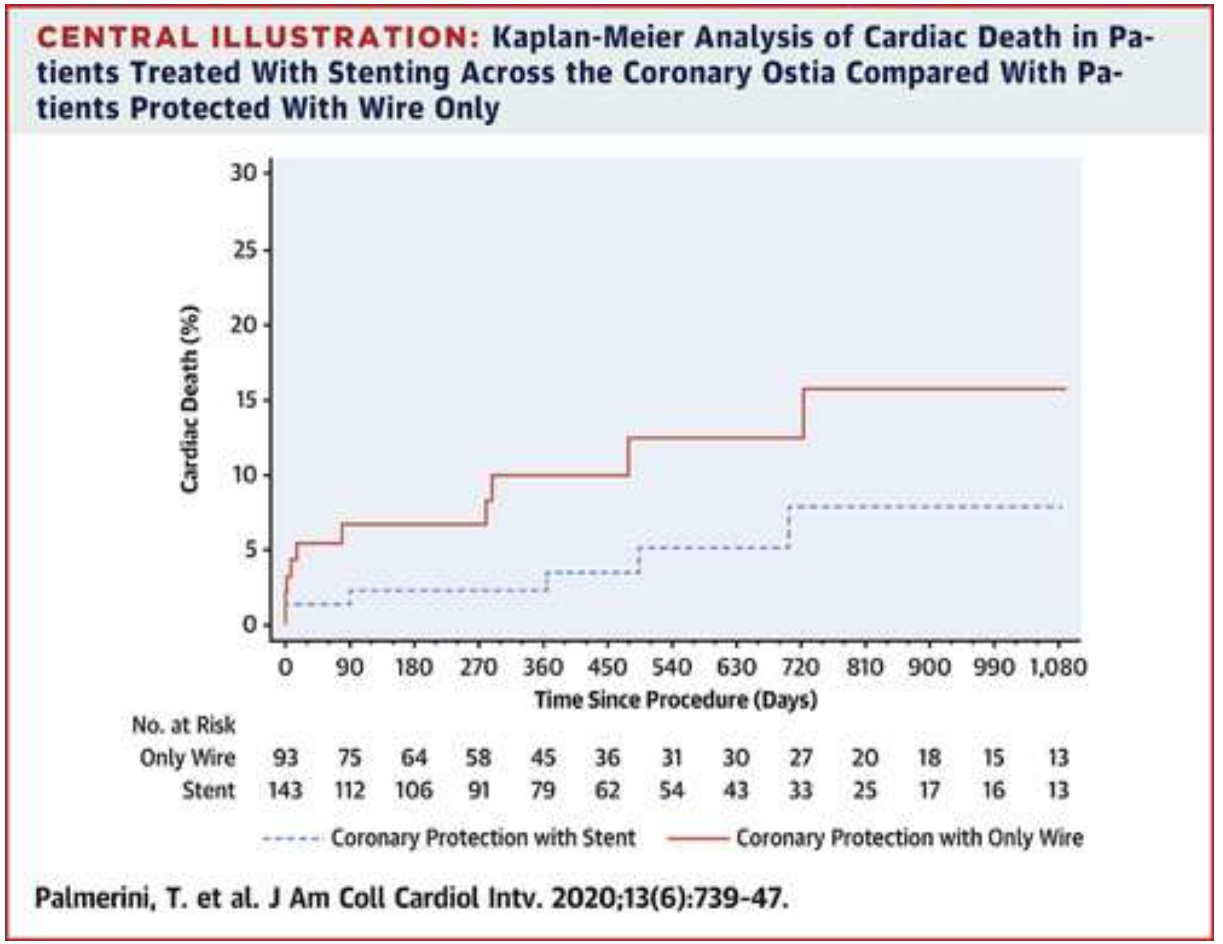
5 Steps for Successful Snorkeling to Prevent Coronary Obstruction Post TAVR



Mercanti, F. et al. J Am Coll Cardiol Intv. 2020;13(6):751-61.

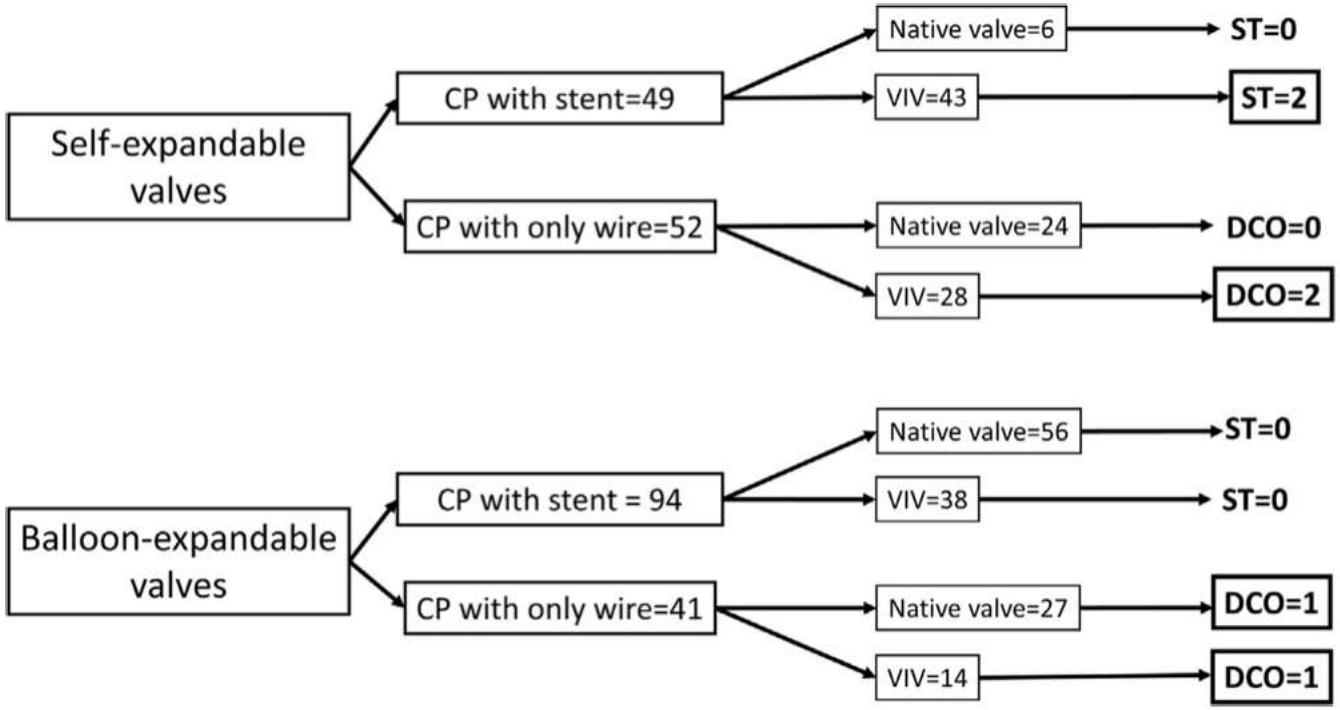
Coronary Protection Stents Versus Wires



Tullio Palmerini et al. *J Am Coll Cardiol Intv* 2020; 13:739-747.

Definite ST and DCO by Valve Type

FIGURE 2 **Definite ST and DCO Stratified by the Type of Valve Implanted and the Type of Procedure Performed**



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Three -Year Clinical Outcome post coronary protection with and without Stents

TABLE 2 Three-Year Clinical Outcomes of Patients Enrolled in the Registry Stratified by Whether They Did or Did Not Undergo Stenting Across the Coronary Ostia

	CP With Stents	CP With Wire	Adjusted HR (95% CI)*	p Value†
All-cause death	13/141 (14.3)	14/93 (26.9)	0.57 (0.25–1.31)	0.18
Cardiac death	6/141 (7.8)	10/93 (15.7)	0.42 (0.14–1.28)	0.13
MI	8/141 (9.8)	2/93 (2.4)	2.35 (0.46–11.87)	0.30
Stroke	5/141 (5.4)	5/93 (6.0)	0.71 (0.19–2.60)	0.60
Cardiac death, MI, or stroke	17/141 (20.1)	15/93 (21.7)	0.79 (0.37–1.68)	0.54

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Snorkel and Chimeny: Baseline Characteristics and Pre procedural Imaging Assessment

TABLE 1 Baseline Characteristics (N = 60)

Age, yrs	81.6 ± 6.7
Male	15 (25.0)
Body surface area, m^2	1.7 ± 0.2
STS PROM, %	6.9 ± 4.6
Prior myocardial infarction	11 (18.3)
Prior PCI	18 (30.0)
Prior CABG	8 (13.3)
Surgical bioprosthetic valve failure	42 (70.0)
Prior pacemaker	11 (18.3)
Atrial fibrillation	21 (35.0)
Pulmonary hypertension	22 (36.7)
NYHA functional class III/IV	54 (90.0)
Glomerular filtration rate, ml/min	46.8 ± 25.3

TABLE 2 Pre-Procedural Imaging Assessment

Echocardiography (N = 60)	
Left ventricular ejection fraction, %	55.5 ± 10.6
Aortic valve	
Peak gradient, mm Hg	64.1 ± 30.1
Mean gradient, mm Hg	39.8 ± 19.3
Valve area, cm^2	0.9 ± 0.5
Predominant stenosis	23 (38.3)
Predominant regurgitation	11 (18.3)
Mixed disease	26 (43.3)
Pulmonary artery pressure, mm Hg	50.5 ± 17.1
Multislice computed tomography (n = 53)	
Native valve annulus	
Area, mm^2	352.2 ± 97.2
Perimeter, mm	67.1 ± 8.7
Maximum diameter, mm	22.4 ± 4.3
Minimum diameter, mm	19.5 ± 3.2
Mean diameter, mm	20.9 ± 3.6
Native aortic root	
Sinus of Valsalva diameter, mm	28.2 ± 4.1
Sinotubular junction diameter, mm	26.2 ± 3.7
Ascending aorta diameter, mm	31.0 ± 4.6
RCA height, mm	10.2 ± 4.1
LCA height, mm	8.2 ± 3.1
VIV: VTC distance	
LMS to SAV, mm	5.5 ± 2.3
RCA to SAV, mm	5.8 ± 2.9

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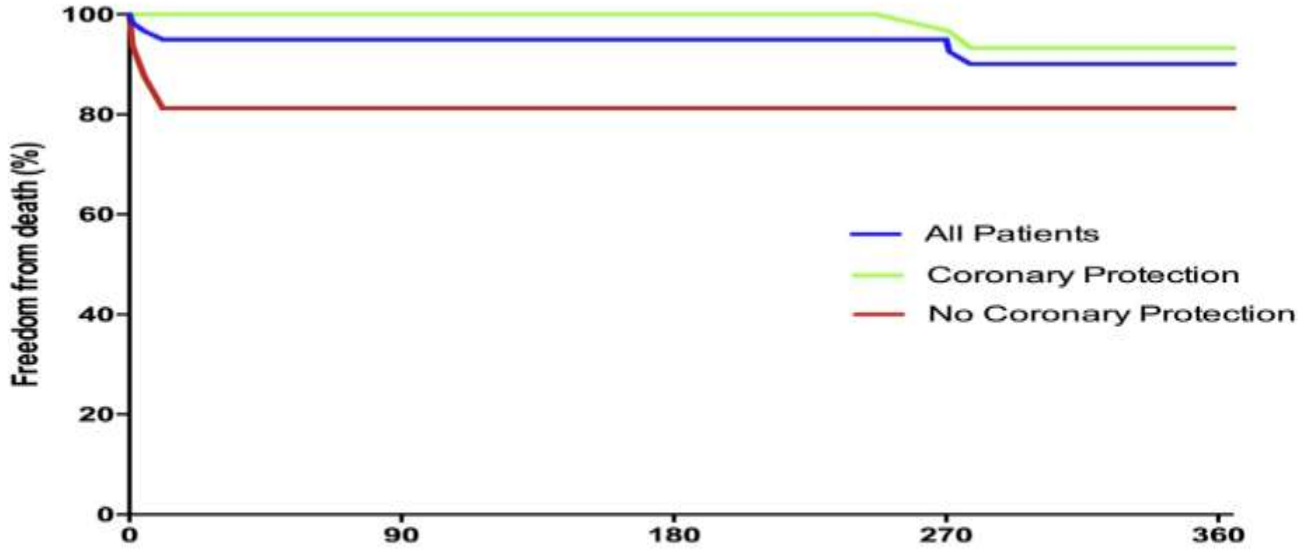
One Year All-Cause Death TAVR with Chimney Stenting

FIGURE 2 One-Year All-Cause Death After TAVR With Chimney Stenting



Patients at risk:					
All Patients	60	57	49	40	35
Protection Yes	44	44	37	31	26
Protection No	16	14	13	10	10

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Predictors of 30 Day Death MI and Cardiogenic Shock

TABLE 6 Predictors of 30-Day Death, Myocardial Infarction, and Cardiogenic Shock

	Univariate Analysis			Multivariate Analysis		
	Odds Ratio	95% CI	p Value	Odds Ratio	95% CI	p Value
Absence of coronary protection	8.81	2.41-32.16	<0.01	7.39	1.95-27.93	<0.01
No VIV	1.41	0.43-4.67	0.6			
Balloon-expandable THV	3.36	1.01-11.18	0.05	2.18	0.56-8.43	0.26
SOV diameter <30 mm	1.93	0.60-6.23	0.27			
Coronary height <10 mm	2.16	0.41-11.37	0.36			
VTC ≤4 mm*	1.54	0.34-6.93	0.58			

*Univariate analysis in the VIV group (n = 42).

CI = confidence interval; SOV = sinus of Valsalva; other abbreviations as in Tables 2 and 3.

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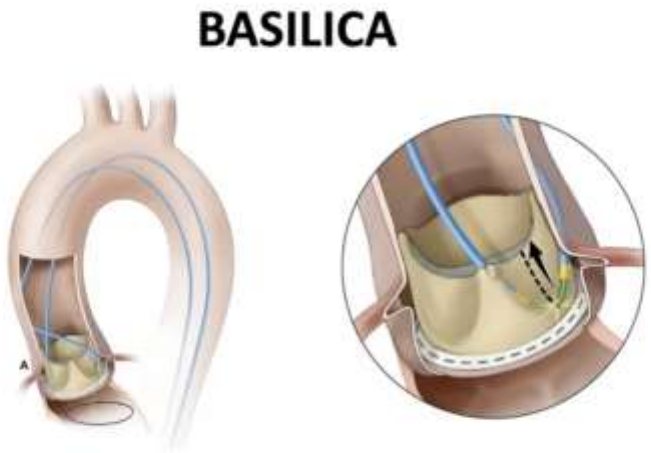
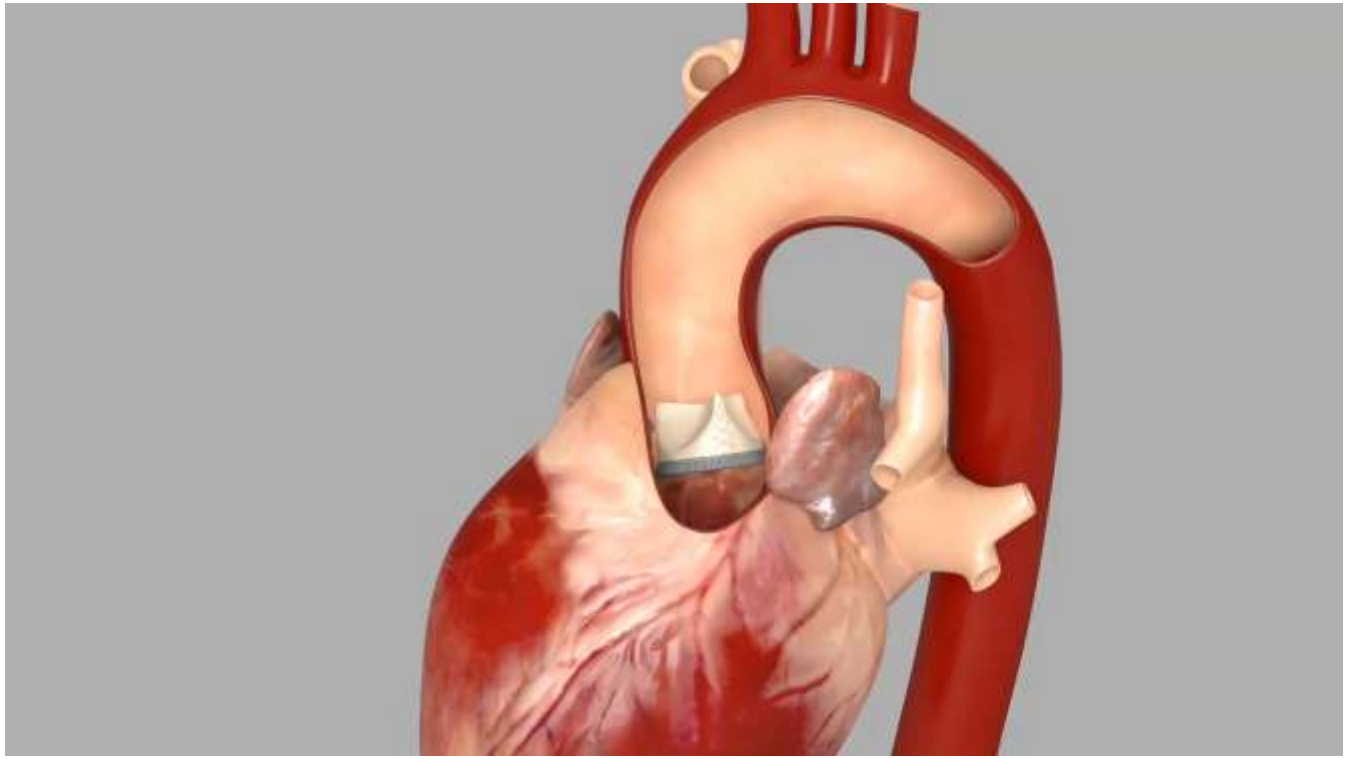
Snorkeling Stents to Prevent Coronary Obstruction Post TAVR

- Chimney stenting is an infrequently used technique to treat or prevent CAO in the setting of TAVR.
- Acute procedural results are encouraging, especially when risk factors for CAO are recognized pre procedure and protection is prepared upfront
- Low incidence of stent thrombosis and the small excess of MIs is reported
- Patients undergoing CP with wires only have a substantial risk for delayed coronary occlusion, which is associated with high rates of mortality
- Stenting across the coronary ostia in patients undergoing TAVR at high risk for coronary obstruction is associated with favorable 3-year survival rates
- Longer term follow-up is required to understand the frequency and impact of late chimney stent failure.

Alternative to Snorkeling and Stenting: Tearing the Leaflet to Prevent Coronary: Basilica

- <u>Advantages</u>
  - Systematically studied
  - Preventive measure
  - No risk of compression impairing flow
- <u>Limitations</u>
  - Technically challenging
  - Requires dedicated equipment





COBRA-TAVR Registry

- International, multi-center, registry of coronary obstruction and protection cases

COBRA-TAVR Registry

- CT Analysis of patients who underwent snorkel stenting or BASILICA
  - Coronary Height (mm)
  - Virtual-VTC (mm)
  - Virtual-VTSTJ (mm)
  - Leaflet relationship to coronary ostium
- Outcomes Analysis
  - Coronary Obstruction
  - Clinical Outcomes

Results: CT Prediction

	Snorkel Stenting n=10*	BASILICA n=10
Threatened Left Coronary Height (mm)	10 ± 3.3	8.7 ± 2.14
Threatened Right Coronary Height (mm)	8.7 ± 2.3	11.5 ± 2.4
Valve-to-Coronary Distance (mm)	3.0 ± .88	3.05 ± 1.07
Valve-to-Sinotubular Junction Distance (mm)	2.54 ± 1.20	2.52 ± 1.15
Leaflet higher than:		
-Base of coronary ostium	100%	100%
-Mid-coronary ostium	90%	90%
-STJ	30%	20%

*2 placed emergently

Results: Clinical Outcomes

	Snorkel Stenting n=10	BASILICA n=10
Clinical Signs of Coronary Obstruction	10	0
Stent Required	7	0
Stent Successfully Relieved Obstruction	6	NA
CABG Required	3	0
Survived to Discharge	8	10

BASILICA IDE

	Per subject n=30	Per leaflet n=37
Successful BASILICA traversal and laceration	28 (93%)	35 (95%)
Survival	30 (100%)	-
Successful first TAVR device implantation	30 (100%)	-
Freedom from Coronary obstruction	30 (100%)	-
Freedom from Emergency surgery or reintervention related to BASILICA TAVR	30 (100%)	-
Procedure success (all of above)	28 (93%)	-

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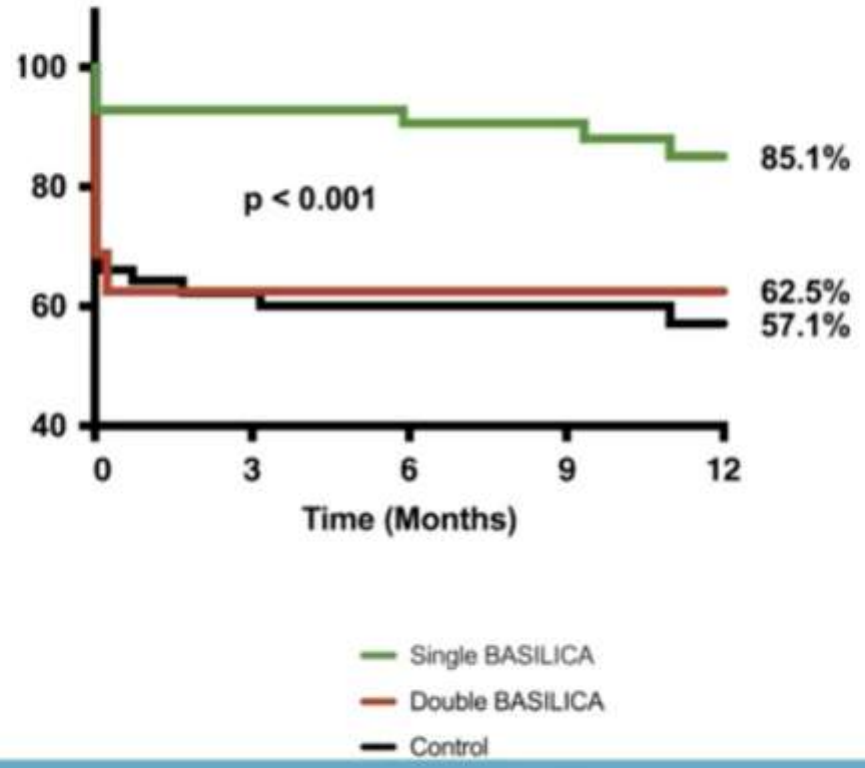
Selected results

	BASILICA (n = 129)	Aortic Valve-in-Valve (n = 2,915)	p-value
Age (years)	75.7 ± 10.1	77.3 ± 10.3	0.1
Height (cm)	163.8 ± 9.7	167.3 ± 9.9	< 0.001
Weight (cm)	79.5 ± 20.3	75.9 ± 17.3	0.03
Male	38.6%	57.3%	< 0.001
DM	40.4%	26%	0.001
Renal failure	33.9%	50.4%	0.001
History of stroke	15.6%	17.2%	0.675
Stentless surgical valve	15.3%	19.5%	0.336
Externally mounted surgical valves (Mitroflow, Trifecta)	68.6%	23%	< 0.001
Surgical valve label size, mm	22.3 ± 2.3	23.3 ± 2.2	< 0.001
Mechanism of failure			< 0.001
Regurgitation	20.2%	29%	
Stenosis	62.3%	41.8%	
Mixed	17.5%	29.2%	
STS Score, %	5.3 ± 3.3	8.4 ± 7.8	< 0.001

Single Versus Double Basilica

Survival free from stroke or coronary obstruction

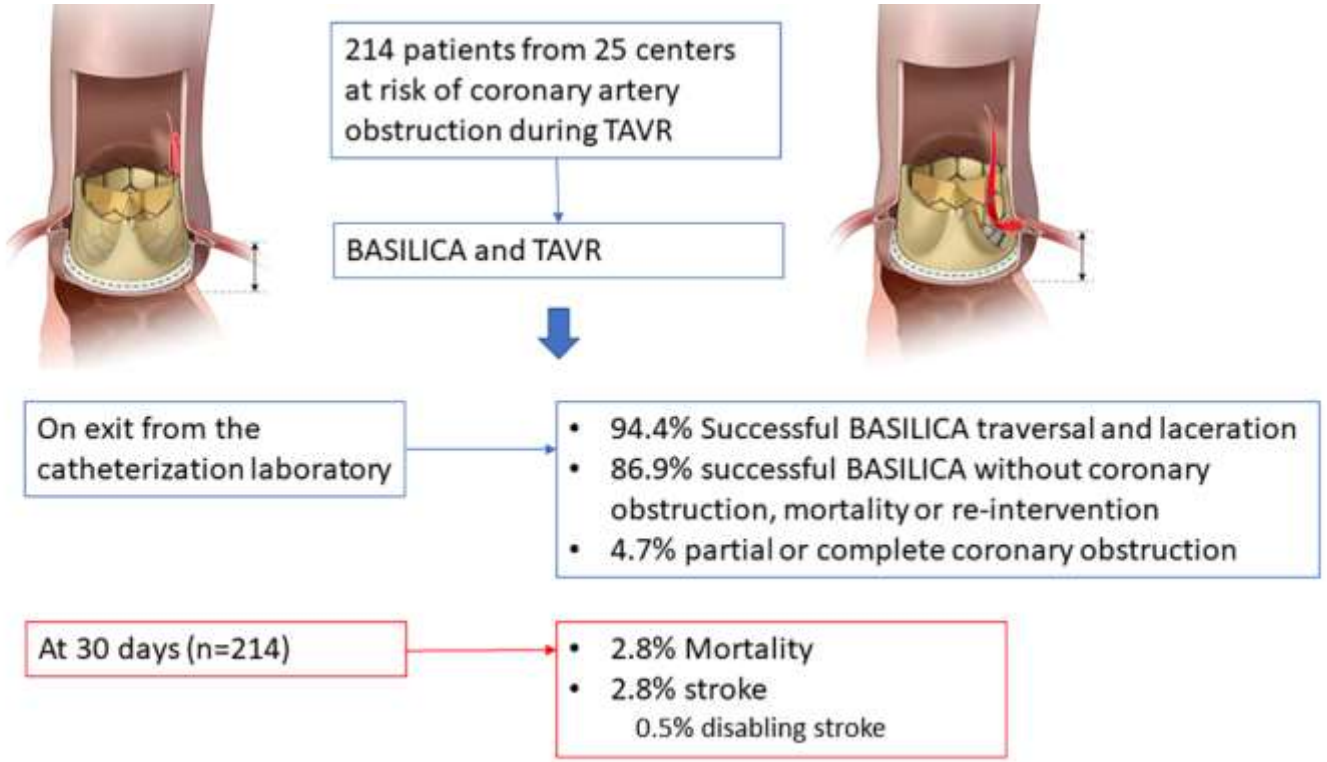


Basilica MedStar Registry

- To determine the safety of the BASILICA procedure
- To determine feasibility of BASILICA in the real-world setting

Methods

- Retrospective, multicenter, single arm registry
- Included patients who had BASILICA to prevent coronary artery obstruction
- Excluded patients in the BASILICA IDE trial
- VARC-2 definitions were used to adjudicate events



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Results: Patient demographics

DEMOGRAPHICS	mean ± SD or %
Age, years	74.9 ± 10.6
Female	68.7%
COMORBIDITIES	
STS PROM %	6.3 ± 5.3
Surgical risk	
Low	4.7%
Intermediate	28.2%
High	54.0%
Extreme	13.1%
Aortic lesion	
Aortic stenosis	85.9%
Aortic regurgitation	14.1%
Aortic valve	
Native	27.2%
Bioprosthetic	72.8%
Prior stroke	14.6%
Prior CABG	31.6%

Results: Procedure

PROCEDURE	Mean ± SD or %
Valve type	
Sapien 3	60.1%
Evolut R/Pro	39.9%
Nominal valve size, mm	23.5 ± 2.3
Access for TAVR	
Transfemoral	91.1%
Transcaval	7.0%
Subclavian/Axillary	0.9%
Carotid	0.9%
Target cusp	
Left solo	68.7%
Right solo	9.8%
Doppio	21.5%
Sentinel cerebral protection	47.7%

Results: Procedural Success

Successful traversal	94.9%
Successful laceration	94.4%
No culprit coronary obstruction	95.3%
Procedure survival	100%
No emergency surgery or re-intervention	93%
Procedural Success	**86.9%**

Results: 30-day safety

Death	2.8%
Stroke	2.8% (0.5% disabling)
Life-threatening bleed	3.3%
Major vascular complication	3.8%
AKI stage 2/3	4.3%
Coronary obstruction (inc non-culprit)	5.7%
Re-intervention	1.4%
VARC-2 30-day safety	**82.8%**

Results: Secondary endpoints

Periprocedural MI	3.3%
Pericardial effusion or cardiac tamponade	0.5%
Procedural hypotension requiring pressors	8.5%
Endocarditis	1.4%
1 year survival (n=124)	**83.9%**

Results: solo vs doppio BASILICA

Outcomes	Solo BASILICA (n=168)	Doppio BASILICA (n=46)	P-value
Procedure success	88.7%	80.4%	0.14
VARC-2 Safety	83.6%	79.5%	0.52
Death	2.4%	4.3%	0.48
All Stroke	2.4%	4.3%	0.49
Disabling Stroke	0.6%	0%	0.51

Results: Bioprosthetic vs Native

Outcomes	Bioprosthetic (n=155)	Native (n=58)	P-value
Procedure success	84.5%	93.1%	0.10
VARC-2 Safety	82.9%	82.1%	0.90
Death	3.3%	1.7%	0.55
All Stroke	3.3%	1.7%	0.54
Disabling Stroke	0.7%	0%	0.54

Results: Cerebral Embolic Protection

Outcomes	Cerebral protection (n=102)	No Cerebral Protection (n=112)	P-value
Procedure success	83.3%	90.2%	0.14
VARC-2 Safety	85.1%	80.7%	0.41
Death	2.0%	4.6%	0.49
All Stroke	1%	4.5%	0.12
Disabling Stroke	0%	0.9%	0.34

Limitations

- Retrospective, site reported data
- Coronary obstruction risk not determined by a core laboratory
- Comparisons are not in matched groups

Conclusions

The largest registry of the BASILICA procedure demonstrates:

- BASILICA is safe, with low rates of stroke and death
- BASILICA is feasible in the “real world” (in centers with experience or appropriate training), with high rates of success and low rates of COA
- This reassuring data should facilitate wider dissemination of the BASILICA procedure at high volume centers
- Snorkel Chimney can be left as a last resort when Basilica cannot be performed
- There is an unmet need for dedicated devices for leaflet tear that can simplify the Basilica approach and protect the coronary from obstruction