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BASILICA Trial: One-Year Outcomes of Transcatheter Electrosurgical Leaflet Laceration to Prevent TAVR Coronary Obstruction

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ORIGINAL ARTICLE

BASILICA Trial

One-Year Outcomes of Transcatheter Electrosurgical Leaflet Laceration to Prevent TAVR Coronary Obstruction

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BACKGROUND: Coronary artery obstruction is a rare, devastating complication of transcatheter aortic valve replacement. Transcatheter electrosurgical aortic leaflet laceration (Bioprosthetic or Native Aortic Scallop Intentional Laceration to Prevent Iatrogenic Coronary Artery Obstruction [BASILICA]) is a novel technique to prevent coronary artery obstruction. We report the 1-year outcomes of the BASILICA trial. Primary end points of 30-day success and safety have been reported previously.

METHODS: The BASILICA trial was a prospective, multicenter, single-arm safety and feasibility study. Subjects with severe native or bioprosthetic aortic valve disease at high or extreme risk for surgery, and high risk of coronary artery obstruction, were included. End points at 1 year included death, stroke, and myocardial infarction. Source data was independently verified and end points independently adjudicated.

RESULTS: Thirty subjects were enrolled between February 2018 and July 2018. At 30 days, BASILICA was successful in 28 subjects (93.3%), there were 3 strokes (10%), including 1 disabling stroke (3.3%), 1 death (3.3%), and 1 periprocedural myocardial infarction (3.3%). Between 30 days and 1 year, there were no additional strokes, no myocardial infarction, and 2 deaths (10% 1-year mortality). No subject needed repeat intervention for aortic valve or coronary disease. Two subjects had infective endocarditis (6.7%), but neither was isolated to the aortic valve. There were no hospital admissions for heart failure. Fourteen (46.7%) subjects required repeat hospital admission for other causes. Aortic valve gradients on echocardiography, New York Heart Association functional class, and Kansas City Cardiomyopathy Questionnaire scores improved from baseline to 30 days and were maintained at 1 year.

CONCLUSIONS: In these subjects with multiple comorbidities and restrictive anatomy that underwent transcatheter aortic valve replacement, there was no late stroke, myocardial infarction, or death related to BASILICA. Mitigation of coronary obstruction remained intact at 1 year and was not related to recurrent readmission. These results are reassuring for patients and physicians who wish to avoid the long-term complications related to snorkel stenting.

REGISTRATION: URL: https://www.clinicaltrials.gov; Unique identifier: NCT03381989.

GRAPHIC ABSTRACT: A graphic abstract is available for this article.

Key Words: aortic valve ■ electrosurgery ■ endocarditis ■ heart failure ■ myocardial infarction

Coronary artery obstruction occurs in 0.7% of all transcatheter aortic valve replacement (TAVR) procedures.[1] The incidence is higher in certain subgroups, especially for TAVR in bioprosthetic valves (valve-in-valve TAVR; 2.3% incidence).[2] Coronary artery obstruction from TAVR is associated with up to 50%

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WHAT IS KNOWN

- BASILICA (Bioprosthetic or Native Aortic Scallop Intentional Laceration to Prevent Iatrogenic Coronary Artery Obstruction) is a novel technique to prevent coronary artery obstruction from transcatheter aortic valve replacement.
- Before this study, only 30-day outcomes had been reported.

WHAT THE STUDY ADDS

- One-year clinical data from the BASILICA trial show no late complications of the BASILICA procedure, particularly no late stroke or coronary artery obstruction.
- These results are reassuring for patients and physicians who wish to avoid the long-term complications related to snorkel stenting.

Nonstandard Abbreviations and Acronyms

BASILICA	Bioprosthetic or Native Aortic Scallop Intentional Laceration to Prevent Iatrogenic Coronary Artery Obstruction
IDE	investigational device exemption
TAVR	transcatheter aortic valve replacement

mortality despite attempted rescue percutaneous coronary intervention or coronary artery bypass surgery, even when successful.[1,2] Therefore, it is important to predict and prevent this complication.

At present, 2 strategies are used for prevention of coronary obstruction. The first is snorkel stenting, where a coronary stent is prepositioned in the coronary artery before TAVR and deployed protruding into the aorta after TAVR. The second strategy, called BASILICA (Bioprosthetic or Native Aortic Scallop Intentional Laceration to Prevent Iatrogenic Coronary Artery Obstruction), uses transcatheter electrosurgery to lacerate the aortic leaflets before TAVR allowing them to splay to the sides after TAVR and, therefore, maintaining coronary perfusion.

The BASILICA technique was investigated in a prospective early feasibility clinical trial, and the 30-day results have been reported previously.[3] Here, we report the 1-year outcomes.

METHODS

Trial Design and Oversight

The BASILICA trial (URL: https://www.clinicaltrials.gov; Unique identifier: NCT03381989) design has been described previously.[3] Briefly, this was an investigator-initiated and sponsored prospective, multicenter, single-arm study of BASILICA, and TAVR. There was 100% independent on-site source data verification and data monitoring. A Clinical Event Committee independently adjudicated the primary end points and death at 1 year. A central core laboratory analyzed baseline and postprocedure echocardiography and computed tomography images up to 30 days but not 1 year. The US Food and Drug Administration granted IDE (Investigational Device Exemption) for the study under the Early Feasibility pathway. The first and senior authors had full access to all the data in the study and take responsibility for its integrity and the data analysis. The data that support the findings of this study are available from the corresponding author upon reasonable request.

Subjects and Eligibility

Thirty subjects were enrolled between February and July 2018 at 4 centers in the United States. Subjects were eligible if they were at least high risk for surgical aortic valve replacement and high risk of coronary artery obstruction from TAVR as determined by a central eligibility committee based on previously published guidelines.[3] The institutional review board at each site and at National Heart, Lung, and Blood Institute approved the study protocol, and all subjects consented to participate in writing.

BASILICA Technique

The BASILICA technique has been described in detail in previous publications.[4,5] Briefly, a guidewire is electrified to traverse the base of the target aortic leaflet. It is snare-externalized and the resulting guidewire loop, after minor benchtop modification to concentrate charge, is further electrified while being retracted together with sheathing guiding catheters. Blood is displaced during electrification with nonionic dextrose solution to concentrate charge on the leaflet and reduce char and thrombus formation.[6] The result is to lacerate the leaflet down the centerline. This may be repeated if double leaflet BASILICA is performed. TAVR is then performed as usual.

Study End Points

The primary end points of the study were procedure success on exit from the catheter laboratory and freedom from major adverse clinical events at 30-days, both as defined by Valve Academic Research Consortium 2. Secondary end points included death, stroke, and myocardial infarction at one year.

Statistical Analysis

All analyses were based on the intention to treat principle with data from all enrolled patients. The sample size of 30 subjects was not derived statistically. Baseline subject and procedural characteristics were summarized as medians and interquartile ranges for continuous variables and counts and percentages for categorical variables. McNemar test and paired *t* test were used to assess the difference in the percentage of New York Heart Association class and Kansas City Cardiomyopathy Questionnaire quality of life measure between baseline, 30 day and 1-year visits, respectively. Statistical analyses were performed using R statistical software 4.0.2 (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

A total of 30 subjects were enrolled in the BASILICA IDE trial (Figure 1). One-year clinical follow-up was available for all the surviving study participants. Table 1 shows the baseline demographics and the coronary obstruction risk for enrolled subjects.

One-Year Clinical End Points

Table 2 lists 30-day and 1-year outcomes for subjects after BASILICA TAVR. Between 30 days and 1 year, there were 2 deaths and no strokes. One subject died on day 110 of bacterial endocarditis with vegetations on all 4 valves, with multiple septic emboli including to the spine and brain, and acute respiratory failure on a background of liver cirrhosis and permanent indwelling central port. This was adjudicated as a cardiovascular death not related to BASILICA. One subject died on day 203 following a fall and head injury. This was adjudicated as a noncardiovascular death not related to BASILICA. No subject suffered myocardial infarction requiring revascularization. There was one late troponin positive event in a subject with known atrial fibrillation and prior myocardial infarction treated with PCI who was admitted 5 months post BASILICA TAVR procedure with palpitations and shortness of breath. She was found to be in atrial fibrillation with a rapid ventricular rate and was treated with rate control medications and continued on existing anticoagulation and aspirin therapy. No subject required repeat intervention for aortic valve or coronary artery disease.

In the first 30 days, there was one major stroke and cardiovascular death (3%) in a patient who suffered distributive shock on induction of anesthesia resulting in systemic inflammatory response syndrome and widespread diffusion restriction and enhancement on brain magnetic resonance imaging. This subject also suffered a periprocedural secondary myocardial infarction with troponin rise and EKG changes that was managed conservatively. There were 2 nondisabling strokes (7%) in subjects who fully recovered baseline neurological function. A Sentinel cerebral embolic protection device was used in 43%, and embolic debris was recovered in 46% of those cases, though no systematic inspection technique was mandated. One patient with nondisabling stroke had a Sentinel in situ.

Including the 2 subjects that died after discharge, 14 subjects required repeat hospital admission in the first year, of which 10 subjects were readmitted between 30 days and 1 year. Four admissions were related to atrial flutter/fibrillation and one to complete AV block. Two subjects had endocarditis, one mentioned above and one with vegetations on the mitral valve. The causes for readmission are detailed in Table 2. Three subjects had multiple admissions, not captured in the table, with gastrointestinal bleed the cause of 2 readmissions, palpitations in 2, and fall in one.

Sub-Group Outcomes

Stroke was seen in 1/7 (14%) doppio BASILICA and 2/23 (8.7%) solo BASILICA during the periprocedural period. Stroke was also observed in 1/13 (7.7%) native and 2/17 (11.8%) bioprosthetic valves.

Three subjects had hypoattenuated leaflet thickening on 30-day computed tomography and were alive at 1 year. Their peak aortic velocities post-TAVR and at 1 year were 2.7 and 2.8 m/s; 3.1 and 3.9 m/s; and 3.7 and 4.2 m/s, respectively. One of these, included above, had a nondisabling procedural stroke.

Three subjects had successful bioprosthetic valve fracture with no stroke or coronary obstruction with residual gradients at 1 year (peak aortic valve velocity

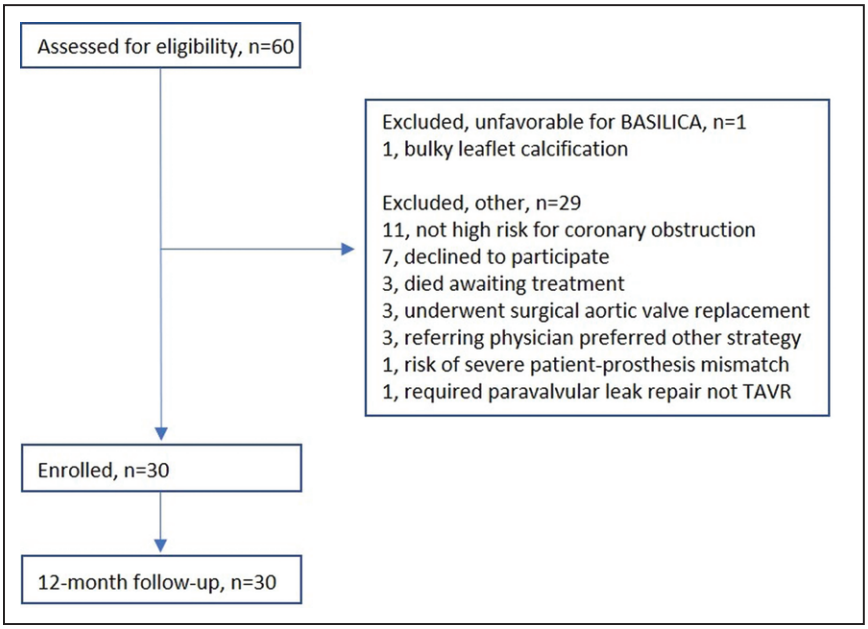

Figure 1. CONSORT flow diagram for the BASILICA trial (Bioprosthetic or Native Aortic Scallop Intentional Laceration to Prevent Iatrogenic Coronary Artery Obstruction).
TAVR indicates transcatheter aortic valve replacement.

Table 1. Baseline Demographics and the Coronary Obstruction Risk for Enrolled Subjects

Demographics	Median (IQR) or n (%; n=30)
Age, y	76 (69–82)
Female	24 (80%)
Comorbidities	
Prior stroke	7 (23%)
Coronary artery disease	19 (63%)
Diabetes	12 (40%)
End-stage kidney disease on dialysis	3 (10%)
Severe pulmonary disease	12 (40%)
Liver cirrhosis	2 (7%)
Hypertension	26 (87%)
Frail	14 (47%)
STS predicted risk of mortality (%)	6 (3–15)
Antiplatelet/anticoagulation	
Aspirin at baseline/discharge/12 mo	73%/87%/77%
$P2Y_{12}$ at baseline/discharge/12 mo	40%/37%/23%
Anticoagulation at baseline/discharge/12 mo	27%/37%/45%
TAVR setting	
Native	13 (43%)
Bioprosthetic	17 (57%)
Coronary obstruction risk on CT	
Coronary artery height, mm	7.2 (5.2–9.7)
Sinus of valsava width, mm	25.9 (24.8–29.0)
VTC, mm	3.3 (2.7–4.0)
VTSTJ, mm	2.2 (0.5–3.1)
Procedure	
Sapien 3	16 (53%)
Evolut R/pro	14 (47%)
Transfemoral access	23 (77%)
Transcaval access	6 (20%)
Percutaneous axillary access	1 (3%)
Solo BASILICA	23 (77%)
Doppio BASILICA	7 (23%)

BASILICA indicates Bioprosthetic or Native Aortic Scallop Intentional Laceration to Prevent Iatrogenic Coronary Artery Obstruction; CT, computed tomography; IQR, interquartile range; STS, Society of Thoracic Surgeons; TAVR, transcatheter aortic valve replacement; VTC, virtual transcatheter to coronary distance; and VTSTJ, virtual transcatheter to sinotubular junction distance.

2.6, 3.2, and 4.2 m/s; mean aortic valve gradient 14, 23, and 34 mm Hg; aortic valve area 2.0, 0.81, and 0.98 cm^2).

Functional and Hemodynamic Results

Functional assessment was complete in 26 subjects (87%) at 1 year. The remaining 4 subjects were alive per local medical notes but without a formal follow-up visit due to travel constraints. Figure 2 shows the change in New York Heart Association class and Kansas City Cardiomyopathy Questionnaire scores from baseline to 30 days to 1 year. Patients have significant improvement

Table 2. Detailed Causes for Readmission

Clinical outcomes	At 30 days (n=30)	At 1 y (n=30)
All death	1 (3.3%)	3 (10%)
Cardiovascular	1 (3.3%)	2 (6.7%)
Noncardiovascular	0 (0%)	1 (3.3%)
All stroke	3 (10%)	3 (10%)
Disabling	1 (3.3%)	1 (3.3%)
Nondisabling	2 (6.7%)	2 (6.7%)
Repeat hospital admission	5 (16.7%)	14 (46.7%)
	Cardiovascular: 3	Cardiovascular: 8
	Stroke: 1 Rhythm of palpitations: 2	Stroke: 1 Rhythm or palpitation: 5 Endocarditis: 2 Heart failure: 0
	Noncardiovascular: 2	Noncardiovascular: 6
	GI bleed: 1 Pneumonia: 1	Anemia or GI bleed: 3 Pneumonia: 1 Septic arthritis: 1 Fall and fracture: 1
Coronary artery obstruction	0 (0%)	0 (0%)
Valve-related dysfunction requiring repeat procedure	0 (0%)	0 (0%)
Need for second valve	0 (0%)	0 (0%)
Spontaneous myocardial infarction	0 (0%)	0 (0%)
Periprocedural myocardial infarction	1 (3.3%)	NA
Any coronary intervention	0 (0%)	0 (0%)
Endocarditis	0 (0%)	2 (7%)
New pacemaker	3 (10%)	3 (10%)
Hemolytic anemia	0 (0%)	0 (0%)

GI indicates gastrointestinal.

in New York Heart Association class and Kansas City Cardiomyopathy Questionnaire scores at 30 days and 1 year compared with baseline (both $P<0.001$), with no significant differences in New York Heart Association and Kansas City Cardiomyopathy Questionnaire summary score between 30-day and 1-year visits.

Echocardiography follow-up was completed in 22 of 27 subjects alive at 1 year (81%). The results are shown in Table 3. As expected, hemodynamics improved with TAVR and were maintained out to one year.

DISCUSSION

The main findings at 30 days for the BASILICA trial were that the procedure was feasible in 93% of patients, the 2 failures relating to heavy target leaflet calcification at the traversal target. No patient had coronary obstruction despite the high predicted risk. There were one death and major stroke (3%) and 2 additional nondisabling strokes (7%).

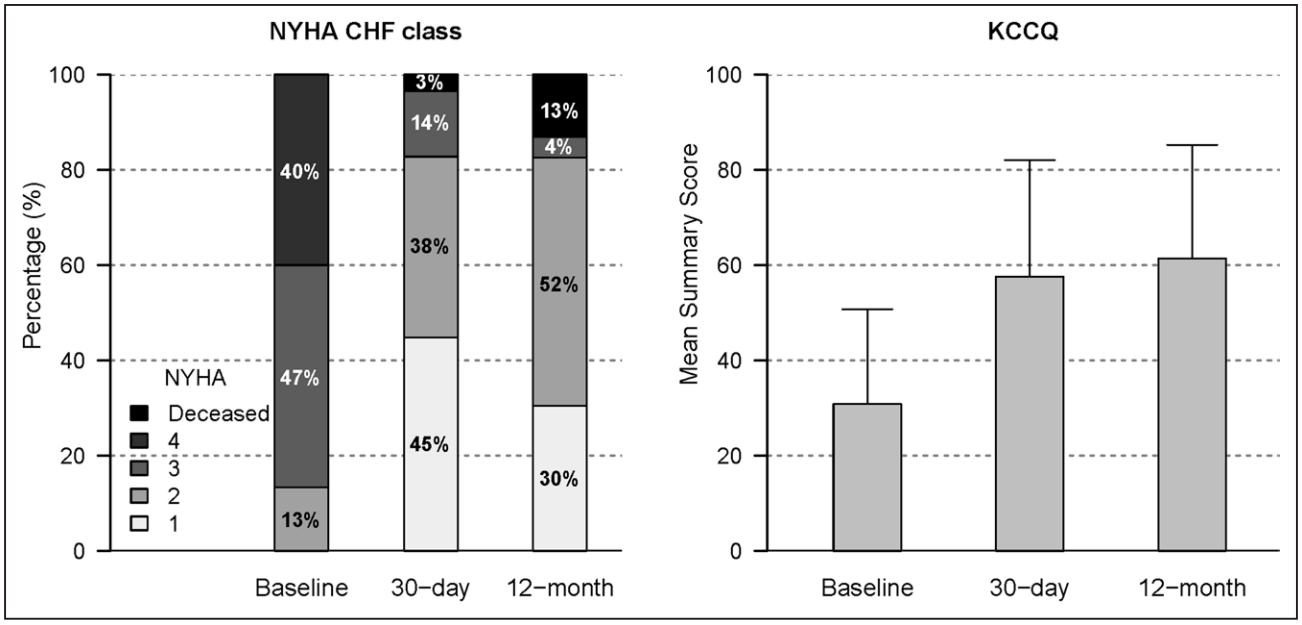

Figure 2. New York Heart Association (NYHA) class and Kansas City Cardiomyopathy Questionnaire (KCCQ) summary scores improved from baseline to 30 days after BASILICA (Bioprosthetic or Native Aortic Scallop Intentional Laceration to Prevent Iatrogenic Coronary Artery Obstruction) transcatheter aortic valve replacement (TAVR) and the improvement was maintained at 1 y. CHF indicates congestive heart failure.

In this article, we reported the 1-year results of the BASILICA trial, and we found there was no late stroke or myocardial infarction after BASILICA TAVR up to one year. There were no repeat interventions. Theoretically, the lacerated leaflet edge could be a nidus for thrombus, infection, and tissue proliferation. The absence of events is, therefore, reassuring and suggests the lacerated leaflets may be benign in the short- and medium-term. The one case of prosthetic valve endocarditis also involved the other 3 cardiac valves and was in the setting of an indwelling catheter.

Another theoretical concern was late mobilization of the leaflet, causing delayed coronary artery obstruction, new late paravalvular leak, or valve embolization. These events were not seen in the BASILICA trial.

Almost half of patients had been admitted to hospital within a year of discharge, although none for heart failure. This readmission rate probably reflects the elderly, frail, and high risk patient cohort treated in the BASILICA trial. This is consistent with data from the TVT registry (Transcatheter Valve Therapy) showing 50% readmission within one year for high risk patients undergoing TAVR.[7]

This study suggests the short- to medium-term outcomes for these patients are similar to high and extreme surgical risk patients without risk of coronary artery obstruction undergoing contemporary TAVR. One-year mortality was 12% and disabling stroke 2.9% at 1 year in the commercial arm (Sapien and Evolut) of the PORTICO IDE trial (Portico Re-Sheathable Transcatheter Aortic Valve System),[8] and 9% mortality and 4% disabling stroke at 1 year in the Evolut arm of SCOPE 2 (Safety and Efficacy Comparison of Two TAVI Systems in a Prospective Randomized Evaluation),[9] compared with 10% mortality and 3.3% disabling stroke at 1 year in the BASILICA trial.

Another option to prevent coronary artery obstruction is snorkel stenting. While the technique is simple and achieves flow in the coronary arteries on exit from the catheter laboratory,[10] stents may be under-expanded or crushed next to the transcatheter heart valve and the long-term durability of this technique is questionable, especially with regards to late stent thrombosis and delayed coronary obstruction.[11] Moreover, re-engaging

Table 3. Results of Echocardiography Follow-Up of Subjects

Echocardiography hemodynamics	Baseline (n=30), median (IQR)	30 days (n=28), median (IQR)	1 y (n=22), median (IQR)
LVEF, %	55 (44–60)	60 (55–63)	61 (55–69)
Aortic valve peak velocity, m/s	4.3 (3.9–4.7)	2.7 (2.4–3.3)	2.6 (2.2–3.2)
Aortic valve mean gradient, mm Hg	43 (37–53)	15 (11–23)	14 (12–23)
Aortic valve area, cm^2	0.7 (0.6–0.8)	1.1 (0.9–1.4)	1.2 (1.0–1.8)
≥ moderate aortic insufficiency	7 (23%)	0 (0%)	1 (5%)

IQR indicates interquartile range; and LVEF, left ventricular ejection fraction.

the coronary artery after snorkel stenting may be impossible, limiting downstream options for these patients.

BASILICA may be more technically demanding than snorkel stenting but our findings suggest there appear no downstream negative sequelae of BASILICA. Coronary access is maintained and may even be easier after BASILICA TAVR than after standalone TAVR as the outer leaflet has been parted. We speculate there may be some positive impact on rates of structural valve degeneration or late thromboembolism as BASILICA may increase flow in the neo-sinus,[12] but this study was not powered to assess this and would require lengthy (5–10 year) follow-up. Although antiplatelet and anticoagulation was not mandated for the BASILICA procedure, many patients received these therapies due to prior comorbidities or by operator discretion after TAVR.

Limitations

This trial was designed to show feasibility of the BASILICA procedure. The main limitations of the trial relate to demonstrating efficacy and safety. Demonstrating efficacy relied on accurate prediction of coronary artery obstruction, which is currently lacking. Despite this shortcoming, no patient developed coronary obstruction despite high predicted risk in all.

TAVR is associated with risk of stroke and vascular complications. It is unknown whether BASILICA increases the risk of stroke. A larger sample size is needed to evaluate whether BASILICA is associated with excess risk of stroke.

Long-term patency of the channel created by BASILICA was assumed by the absence of cardiovascular death, coronary obstruction, myocardial infarction, or repeat intervention, but no dedicated imaging was mandated to confirm this. Indeed, noninvasive imaging is unlikely to make this determination.

An intention to treat analysis was used throughout for this study as there was no control group, and we felt this reflected the procedure risk better than an as-treated analysis in these subjects. In the 2 subjects where BASILICA failed, multiple traversal attempts were made but without success, involving extra manipulation of leaflets, radiofrequency energy delivered, and time taken. Furthermore, in one subject, double BASILICA was planned, and BASILICA was successful in the left cusp but failed in the right cusp. We classified this as a failure of BASILICA in the patient. These would create ambiguity in an as-treated analysis. The one patient who did not have BASILICA had multiple hospital admissions with gastrointestinal bleeding and palpitations as reported in this article.

Finally, the sample size and event rate were too small for meaningful comparison in outcomes between native and bioprosthetic valves, solo and doppio BASILICA, or between subjects with and without hypoattenuated leaflet thickening at 30 days.

Future Directions

A randomized controlled trial may help clinicians decide between BASILICA, snorkel stenting, or surgery when faced with intermediate or high surgical risk patients with high risk of TAVR related coronary artery obstruction. However, such a trial is unlikely to be conducted due to cost and perceived lack of equipoise. Operators who are facile with the BASILICA procedure are reluctant to revert to deploying snorkel stents. Data from BASILICA registries will add to our understanding of the safety of the procedure, particularly whether BASILICA is associated with an excess risk of stroke, and whether cerebral embolic devices may be useful in this setting.

The BASILICA technique has undergone modest refinement since this trial. Dedicated pachyderm-shaped guiding catheters assist in the technique and reduce procedure time.[13] Further dedicated device development for leaflet laceration is likely to make the procedure easier and more reproducible. In performing these procedures and assessing these registries, it is important to assure appropriate technique including use of dextrose-water flush to minimize char and thromboembolism during transcatheter electrosurgery. Dextrose or iodine contrast injection during attempted traversal may enhance traversal success beyond what was observed in this protocol. Favorable and unfavorable patient anatomic features, in the opinion of the authors, are tabulated in Table 4.

As TAVR is offered to progressively lower-risk patients, the risk of TAV-in-TAV induced coronary obstruction is expected to increase over time. The applicability of BASILICA for failed transcatheter heart valves is potentially large.

Table 4. Favorable and Unfavorable Anatomic Features of Patients

Anatomy	Favorable for BASILICA	Unfavorable for BASILICA
Calcium	Typical calcium pattern which spares the nadir of the leaflet	Confluent calcium at the leaflet nadir
		Bulky calcium mass on the leaflet
Bioprosthesis	Commissures aligned with native commissures	Bioprosthetic valve post in-front of coronary artery ostium
Access	Femoral access for BASILICA catheters preferred for ergonomics	Nonfemoral access (femoral artery or transcaval) for double leaflet BASILICA
Coronary obstruction risk	Single leaflet BASILICA	Double BASILICA not recommended for new operators in their first 2–3 cases
	Risk from sinus sequestration	

BASILICA indicates Bioprosthetic or Native Aortic Scallop Intentional Laceration to Prevent Iatrogenic Coronary Artery Obstruction.

Early benchtop studies suggest that BASILICA may not be suitable in all patients undergoing TAV-in-TAV because of transcatheter heart valve design, and the randomness of commissural alignment in the common transcatheter heart valves.[14] In appropriately selected cases, particularly where the risk is from sinus sequestration, BASILICA may be useful in preventing coronary obstruction in TAV-in-TAV.

Conclusions

There were no late complications of BASILICA observed in the BASILICA IDE trial, including no stroke, myocardial infarction, or repeat intervention. There were no BASILICA-related deaths. The lacerated leaflets did not appear to be a persistent nidus for thrombosis or infection. Mitigation of coronary obstruction remained intact at 1 year and was not related to recurrent readmission in this sick and frail patient group. Coronary artery obstruction remains uncommon, and this small early feasibility trial cannot exclude rare complications. Unlike the lifetime management burden of a snorkeled coronary stent with antiplatelet therapy, difficult coronary access, and risks of restenosis and stent thrombosis, there does not appear to be any specific management required after a split leaflet.

ARTICLE INFORMATION

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Disclosures

Drs Khan, Rogers, and Lederman are co-inventors on patents, assigned to National Institutes of Health (NIH), on catheter devices to lacerate valve leaflets. Dr Khan has proctored for Edwards Lifesciences and Medtronic. Dr Greenbaum is a proctor for Edwards Lifesciences, Medtronic, and Abbott Vascular. He has equity in Transmural Systems. Dr Babaliaros is a consultant for Edwards Lifesciences, Abbott Vascular and Transmural Systems, and his employer has research contracts for clinical investigation of transcatheter aortic and mitral devices from Edwards Lifesciences, Abbott Vascular, Medtronic, St Jude Medical, and Boston Scientific. Dr Rogers is a consultant/proctor for Edwards Lifesciences and Medtronic. He has equity in Transmural Systems. Dr Eng is a proctor for Edwards Lifesciences. Dr Waksman is a consultant for Medtronic and is a consultant and receives grant support from Abbott Vascular. Dr Dvir is a consultant for Edwards Lifesciences, Medtronic and Abbott Vascular. Dr Lederman is the principal investigator on a Cooperative Research and Development Agreement between NIH and Edwards Lifesciences on transcatheter modification of the mitral valve. The other authors report no conflicts.

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