Supplement:

The BASILICA Trial: A prospective multi-centre cohort study of intentional leaflet laceration before transcatheter aortic valve implantation (TAVI) to prevent coronary obstruction

Study selection criteria

Inclusion Criteria

- Adults age ≥ 21 years
- High or extreme risk of surgical aortic valve replacement according to the local multidisciplinary heart team
- Undergoing TAVI for valve-in-valve or native aortic valve failure ("on-label" TAVI)
- Deemed likely to suffer coronary artery obstruction from TAVI according to multidisciplinary heart team
- Concurrence of the study eligibility committee

Exclusion criteria

- Subjects unable to consent to participate, unless the subject has a legally authorized representative
- Excessive target aortic leaflet calcification or masses on baseline CT
- Survival despite successful procedure expected < 12 months
- Planned concurrent valve intervention in the same setting (such as transcatheter mitral valve therapy or paravalvular leak therapy)
- Subjects unwilling to participate or unwilling to return for study follow-up activities.
- Pregnancy or intent to become pregnant prior to completion of all protocol follow-up procedures

Trial endpoints

Primary efficacy endpoint

The **primary efficacy endpoint** is procedure success (measured at exit from the catheterization laboratory). All of the following must be present:

- Successful BASILICA traversal and laceration of the intended aortic leaflet; and
- Absence of procedural mortality; and
- Successful access, delivery, and retrieval of the BASILICA device system; and
- Successful TAVI device implantation; and
- Absence of acute life-threatening ostial coronary artery obstruction (by immediate hemodynamics, by angiography, and by iFR <0.89 if obtained)
- Freedom from emergency cardiac surgery or reintervention related to the BASILICA TAVI procedure, including attempted implantation of coronary artery stents to treat TAVI-induced coronary artery obstruction.

Additional details about primary endpoint

Valve post-dilatation is not considered unplanned re-intervention. When pre-positioned coronary artery stents are not able to be retrieved, they may be implanted without impacting the primary endpoint.

Primary safety endpoint

The **primary safety endpoint** is freedom from major adverse clinical events (MACE) according to VARC-2 at 30days:

- All-cause mortality
- All stroke (disabling and non-disabling)
- Life-threatening bleeding
- Acute kidney injury—Stage 2 or 3 (including renal replacement
- therapy)
- Coronary artery obstruction requiring intervention
- Major vascular complication
- Valve-related dysfunction requiring repeat procedure (BAV, TAVI, or SAVR)

Additional endpoints

- Technical success, defined as clinical success irrespective of coronary artery stenting
- Clinical success without stroke, as determined by site physicians
- Technical success of BASILICA only (delivery and removal of BASILICA catheter equipment, traversal, and laceration of intended aortic leaflet)
- Coronary artery obstruction measured as instantaneous wave-free pressure ratio (iFR) or related measurements using a solid-state pressure-transducer guidewire, if measured
- Survival to discharge, to 30d, and to 12mo
- Neurological events as reported by the site clinicians
- Access and vascular complications
- Peri-procedural and spontaneous acute myocardial infarction
- Pericardial effusion or tamponade
- VARC-2 bleeding complications
- Acute kidney injury
- Freedom from hemolytic anemia related to BASILICA TAVI
- BASILICA Device or Procedure related technical failure: acute embolism, mitral valve injury, traversal into left atrium, coronary artery injury induced by BASILICA, etc.
- Rotational orientation of transcatheter heart valve commissures with regard to coronary artery ostia
- Hemodynamic instability caused by BASILICA before TAVI
- TAVI thrombosis on CT or echocardiography during follow-up
- Endocarditis during follow-up
- Outcomes for laceration of native versus surgical aortic valves, for single versus double scallop laceration, and for procedures with versus without bioprosthesis intentional overexpansion

Enrolling Sites

Site	City	Principal Investigator	Subjects enrolled
Emory University Hospital	Atlanta	Vasilis Babaliaros	10 Subjects
University of Washington	Seattle	Danny Dvir	10 Subjects
Henry Ford Hospital Systems	Detroit	Adam Greenbaum and Marvin Eng	7 subjects
Medstar Washington Hospital Center	Washington DC	Toby Rogers	3 subjects

Online Table. Coronary obstruction risk factors and BASILICA technical success for 30 subjects

Age	Sex	TAVI setting	High risk features of bioprosthesis	Aortic valve mean gradient	Aortic regurg. severity	Annulus area (mm^2)	LCA height (mm)	RCA height (mm)	Left SOV width (mm)	Right SOV width (mm)	LCA VTC (mm)	RCA VTC (mm)	TAVI access	THV implanted	Valve size (mm)	# of leaflet targets	1st leaflet attempted	1st leaflet successful traversal	1st leaflet successful laceration	2nd leaflet attempted	2nd leaflet successful traversal	2nd leaflet successful laceration
83	F	Magna		51	Mild	260	9.7	15.7	30.3	27.7	7.8	5.0	Femoral	Evolut R	23	2	Right	Yes	Yes	Left	Yes	Yes
75	F	Magna		61	Mild	262	3.7	0.0	24.4	25.3	2.0	3.7	Transcaval	Evolut R	23	2	Right	Yes	Yes	Left	Yes	Yes
67	M	Magna Ease		41	None	265	5.2	6.4	25.5	24.9	4.4	4.0	Femoral	Evolut Pro	23	2	Right	Yes	Yes	Left	Yes	Yes
82	F	Magna Ease		43	None	268	6.3	8.9	24.6	23.9	2.2	4.0	Femoral	Sapien 3	23	2	Right	Yes	Yes	Left	Yes	Yes
92	F	Mitroflow	Ext. leaflets	33	Moderate	259	8.9	6.6	26.2	23.2	2.2	2.9	Femoral	Sapien 3	20	2	Right	Yes	Yes	Left	Yes	Yes
77	F	Mitroflow	Ext. leaflets	56	None	290	5.4	8.7	25.2	25.1	1.7	3.8	Femoral	Sapien 3	20	2	Right	No	N/A	Left	Yes	Yes
79	F	Mitroflow	Ext. leaflets	81	None	305	5.7	9.7	28.8	33.3	5.5	3.2	Transcaval	Evolut R	23	1	Left	Yes	Yes			
67	F	Trifecta	Ext. leaflets	43	Mild	277	4.1	5.6	25.9	24.2	3.4	3.9	Femoral	Evolut R	23	1	Left	Yes	Yes			
82	F	Trifecta	Ext. leaflets	76	None	226	2.0	4.9	24.3	21.8	4.0	2.8	Axillary	Evolut R	23	1	Left	Yes	Yes			
69	F	Trifecta	Ext. leaflets	73	Moderate	260	2.7	5.3	25.1	22.9	5.7	3.3	Femoral	Evolut R	23	1	Left	No	N/A			
62	M	Freestyle	Stentless	17	Moderate	393	7.2	12.1	31.1	39.2	3.3	4.6	Femoral	Evolut Pro	29	1	Left	Yes	Yes			
69	M	Toronto SPV	Stentless	9	Severe	477	3.9	4.2	30.0	31.6	3.8	5.2	Femoral	Evolut R	29	1	Left	Yes	Yes			
83	F	Magna		43	Moderate	262	12.3	11.7	26.4	27.2	2.9	5.6	Femoral	Evolut R	23	1	Left	Yes	Yes			
76	F	Magna		42	None	243	2.5	4.3	29.0	28.1	3.0	7.2	Femoral	Evolut R	23	1	Left	Yes	Yes			
74	M	Magna		37	Mild	489	3.3	6.9	28.6	27.9	3.2	5.1	Femoral	Sapien 3	26	1	Left	Yes	Yes			
73	F	Magna Ease		38	None	259	1.7	8.2	26.9	24.8	4.3	2.9	Femoral	Evolut R	23	1	Right	Yes	Yes			
81	M	Mosaic		45	None	293	13.7	6.7	32.6	28.7	5.5	4.2	Transcaval	Sapien 3	23	1	Right	Yes	Yes			
74	F	Native		45	Mild	307	6.5	8.1	27.2	25.9	3.8	3.9	Transcaval	Sapien 3	23	2	Right	Yes	Yes	Left	Yes	Yes
59	F	Native		39	Mild	227	12.2	11.3	20.8	20.5	3.5	2.4	Femoral	Evolut R	23	1	Right	Yes	Yes			
82	F	Native		43	Mild	306	11.4	12.4	26.0	25.8	5.7	2.3	Femoral	Sapien 3	20	1	Right	Yes	Yes			
62	F	Native		59	Mild	366	12.7	9.6	27.3	22.2	2.9	3.3	Femoral	Sapien 3	23	1	Right	Yes	Yes			
85	M	Native		45	Moderate	585	10.1	10.4	33.9	33.2	3.9	5.0	Femoral	Sapien 3	29	1	Left	Yes	Yes			
76	F	Native		34	Mild	471	13.2	11.4	31.8	31.0	4.1	5.9	Femoral	Sapien 3	26	1	Left	Yes	Yes			
76	F	Native		26	None	536	12.0	12.0	29.0	32.6	2.6	3.1	Transcaval	Sapien 3	26	1	Left	Yes	Yes			
61	F	Native		53	Mild	234	10.9	10.1	20.7	20.3	1.6	1.3	Transcaval	Sapien 3	20	1	Left	Yes	Yes			
75	F	Native		19	None	379	7.8	10.3	25.9	25.3	2.7	4.5	Femoral	Sapien 3	23	1	Left	Yes	Yes			
52	F	Native		48	Moderate	522	5.8	7.8	29.8	29.5	3.1	3.5	Femoral	Sapien 3	26	1	Left	Yes	Yes			
77	F	Native		46	Mild	274	13.3	13.8	24.3	23.1	2.7	4.7	Femoral	Evolut Pro	23	1	Left	Yes	Yes			
79	F	Native		22	None	446	8.8	13.8	29.0	29.7	1.7	4.3	Femoral	Sapien 3	26	1	Left	Yes	Yes			
82	F	Native		53	None	450	4.6	12.3	30.9	31.2	3.2	4.1	Femoral	Sapien 3	26	1	Left	Yes	Yes			

Online Figure 1. Procedure Hemodynamics

Mean arterial pressures for each patient is shown at baseline, before and after (*solo* or *doppio*) laceration, and after TAVI for native and bioprosthetic valves. Small decrements in mean arterial pressures were seen more often in native aortic valves. Only two subjects required transient increase in vasopressor support prior to TAVI.