

#### **BASILICA COMPLICATION CASE**

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MOST



Presented by A Greenbaum, SHDS 2018

# Predicting coronary obstruction is complicated

#### Table 1. Possible Risk Factors for Coronary Obstruction AfterValve-in-Valve Implantation



#### Presented by A Greenbaum, SHDS 2018

#### VTC for patients <4mm



#### Presented by A Greenbaum, SHDS 2018

**The BASILICA concept** 

#### BIOPROSTHETIC AORTIC SCALLOP INTENTIONAL LACERATION TO PREVENT LATROGENIC CORONARY ARTERY OBSTRUCTION











#### Translation to clinical care



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## **BASILICA IDE trial**



- Prospective, single arm, multicenter, early feasibility study (EFS) IDE sponsored by NHLBI
- Investigator-initiated, on-site data monitoring, core lab analysis, and CEAC\* adjudicated end points
- 30 subjects at 4 sites
- Inclusion criteria
  - Undergoing on-label TAVR for native severe aortic stenosis or bioprosthetic valve failure
  - Deemed likely to suffer coronary artery obstruction
- Exclusion criteria
  - Excessive target leaflet calcification or masses
- Primary efficacy endpoint:
  - Successful traversal and laceration of intended leaflets with no coronary obstruction, AND
  - Successful TAVR without emergency surgery or re-intervention
- Primary safety endpoint:
  - Freedom from VARC-2 MACE through 30 days





### Primary endpoint

	Per patient 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%)	-
Coronary obstruction	0 (0%)	-
Emergency surgery or reintervention related to BASILICA TAVR	0 (0%)	
Technical success	28 (93%)	-





### In-hospital outcomes

	n=30		
In-hospital mortality	1 (3%) Multi-organ failure, bospice, death day 17		
Stroke	3 (10%)		
Myocardial infarction	0		
Coronary obstruction	0		
AKI stage 2/3	1 (3%)		
Major bleeding or vascular complication	2 (7%) 1 iliac artery dissection requiring stent 1 access site hematoma requiring blood transfusion		
Permanent pacemaker	2 (6%)		
Emergency surgery	0		
PVL requiring re-intervention	0		

2019



Khan JM et al, JACC Intv 2019

#### Case

- 83F
- Asthma/HTN/PPM
- 2000 AVR Freestyle #23
  - Prolonged post op course
  - Reoperation for bleeding
  - Slow rehabilitation
- 2018 recurrent CHF
  - NYHA III
  - Failing AVR with severe Al/global LV dysfunction/ RVSP 55 mm Hg
- Assessed by two surgical centres as high/prohibitive risk for redo
  - Patient herself declined redo SAVR
  - DNR no ICU, no prolonged intubation

#### CT measurements

- Annulus
  - Area 335mm2 Perimeter 64.2 mm. Diameters (20.4-20.6mm)
- Sinus diameters 24-26 mm
- Coronary Heights
  - LCA 7.5, RCA 12 mm
- VTC (assuming 20 mm annulus diameter)
  - LCA 3.5 RCA 3.0
- STJ diameter 25.5 mm
- STJ Height 16.5 mm

#### Pre MDCT, MPR image Leaflets extend above both coronary ostium



# Evolut PRO/ Evolut R Patient Selection

Valve Size Selection	Evolut R/PRO TAV			Evolut R TAV
Size	23 mm	26 mm	29 mm	34 mm
Annulus Diameter	18 – 20 mm	20 – 23 mm	23 – 26 mm	26 - 30 mm
Annulus Perimeter ( $\pi$ x Diameter)	56.5 – 62.8 mm	62.8 – 72.3 mm	72.3 – 81.7 mm	81.7 – 94.2 mm
Sinus of Valsalva Diameter (Mean)	≥ 25 mm	≥ 27 mm	≥ 29 mm	≥ 31 mm
Sinus of Valsalva Height (Mean)	≥ 15 mm			≥ 16 mm

#### **BASILICA Basics**

INTERVENTIONS FOR VALVULAR DISEASE AND HEART FAILURE

**Bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction. Part 1: how to evaluate patients for BASILICA** 



Ikki Komatsu, MD; G. Burkhard Mackensen, MD, PhD; Gabriel S. Aldea, MD; Mark Reisman, MD; Danny Dvir\*, MD

INTERVENTIONS FOR VALVULAR DISEASE AND HEART FAILURE

**Bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction. Part 2: how to perform BASILICA** 



ished

Jaa April 2019

Ikki Komatsu, MD; G. Burkhard Mackensen, MD, PhD; Gabriel S. Aldea, MD; Mark Reisman, MD; Danny Dvir\*, MD

#### Pre coronary, aorta, leg angiograms



### VTSTJ/ VTC for SapeinS3 23mm

RCA VTC 1.5



LCA VTC 1.5

### VTSTJ/ VTC for SapeinS320mm

LCA VTC 3.5 RCA VTC 3.0 Double Oblique (MPR) 🜩 0 Durso **3**mensio

### Angiogram



Access; Rt: 18Fr Gore Lt: 8Fr,6Fr double puncture

#### Pre LCC Side/Front view



-AL3.5 8Fr guiding catheter -25mm Snare guide in 6Fr MP LAO 37 CRA 36



Usually start with higher risk coronary cusp first RAO 25 CAU 33

#### Traverse catheter positioning





-AL3.5 8Fr guiding catheter+ 5FR JR4.0 120cm, AstatoXS20mm 300cm, Piggyback

#### Pachyderm Shaped Dedicated Guides



J Lisko, TVT 2019

#### LCC traversal, wire snaring





Traverse with 30W

### LCC injection -good center and deep traversal





#### Pre RCC Side/Front view





#### RAO 40 CAU 33

#### LAO 2 CAU 10

#### Traverse catheter positioning





-MB1 8Fr guiding catheter+ 5FR JR4.0 120cm, AstatoXS20mm 300cm, Piggyback

#### RCC traversal, wire snaring



Traverse with 30W



#### Bring V shape



#### Double V shape



#### Lt->Rt leaflet laceration with 50W







Presented by A Greenbaum, SHDS 2018

### THV implantation











### High vs Deep implant



### Tough Lessons Learned

- SWEAT THE DETAILS
- Attention to THV structure/dimensions
  - Skirt!
  - 3D modelling?
- Attention to depth
- ?Consider commissural alignment possibilities
- Release in:
  - 'ideal position' AND
  - 'ideal imaging angle'

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