2017 MID-ATLANTIC
CONFERENCE

7th ANNUAL CURRENT CONCEPTS IN
VASCULAR THERAPIES

2017

David Dexter
MD FACS
Sentara Vascular Specialists
Assistant Professor of Surgery EVMS

Peripheral Complications of TAVR

TAVR Complications

JACC
JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY

Reported Complications Rates range from 8% to 15%

Predictors of Complications

- Gender
- Calcification
- Diameter
- Sheath Size

Percutaneous Aortic Valve Replacement

Vascular Outcomes With a Fully Percutaneous Procedure

Vascular Complications After Transcatheter Aortic Valve Replacement

Insights From the PARTNER (Placement of AoRTic TraNscathetER Valve) Trial

IMPACT OF LOW-PROFILE SHEATHS ON VASCULAR COMPLICATION AND BLEEDING DURING TRANSFEMORAL TRANSCATHETER AORTIC VALVE REPLACEMENT

EVMS
Eastern Virginia Medical School
Teaching. Discovering. Caring.™

How Do We Keep Track?

Updated standardized endpoint definitions for transcatheter aortic valve implantation: The Valve Academic Research Consortium-2 consensus document

A. Pieter Kappetein, Stuart J. Head, Philippe Généreux, Nicolo Piazza, Nicolas M. van Mieghem, Eugene H. Blackstone, Thomas G. Brott, David J. Cohen, Donald E. Cutlip, Gerrit-Anne van Es, Rebecca T. Hahn, Ajay J. Kirtane, Mitchell W. Krucoff, Susheel Kodali, Michael J. Mack, Roxana Mehran, Josep Rodés-Cabau, Pascal Vranckx, John G. Webb, Stephan Windecker, Patrick W. Serruys, Martin B. Leon

* The Valve Academic Research Consortium (VARC) consists of representatives from several independent Academic Research Organizations, several Surgery and Cardiology Societies, members of the US Food and Drug Administration (FDA), and several independent experts. However, it is not a society document. Neither the societies nor the FDA has been asked to endorse the document.

- This document provides an overview of risk assessment and patient stratification that need to be considered for accurate patient inclusion in studies.
- Working groups were assigned to define the following clinical endpoints:
  - mortality, stroke, myocardial infarction, bleeding complications, acute kidney injury, vascular complications, conduction disturbances and arrhythmias, and a miscellaneous category including relevant complications not previously categorized.

VARC-2 Complications

Major vascular complications

- Any aortic dissection, aortic rupture, annulus rupture, left ventricle perforation or new apical aneurysm/pseudoaneurysm.
- Access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arteriovenous fistula, pseudoaneurysm, haematoma, irreversible nerve injury, compartment syndrome and/or percutaneous closure device failure) leading to death, life-threatening or major bleeding,* visceral ischaemia or neurological impairment.
- Distal embolization (noncerebral) from a vascular source requiring surgery or resulting in amputation or irreversible end-organ damage.
- Use of unplanned endovascular or surgical intervention associated with death, major bleeding, visceral ischaemia or neurological impairment.
- Any new ipsilateral lower extremity ischaemia documented by patient symptoms, physical exam and/or decreased or absent blood flow on lower extremity angiogram.
- Surgery for access site-related nerve injury.
- Permanent access site-related nerve injury.

Minor vascular complications

- Access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arteriovenous fistula, pseudoaneuysms, haematomas and/or percutaneous closure device failure) not leading to death, life-threatening or major bleeding, visceral ischaemia or neurological impairment.
- Distal embolization treated with embolectomy and/or thrombectomy and not resulting in amputation or irreversible end-organ damage.
- Any unplanned endovascular stenting or unplanned surgical intervention not meeting the criteria for a major vascular complication.
- Vascular repair or the need for vascular repair (via surgery, ultrasoundguided compression, transcatheter embolization or stent-graft).

Percutaneous closure device failure

- Failure of a closure device to achieve haemostasis at the arteriotomy site leading to alternative treatment (other than manual compression or adjunctive endovascular ballooning).

Valve Academic Research Consortium (VARC-2)

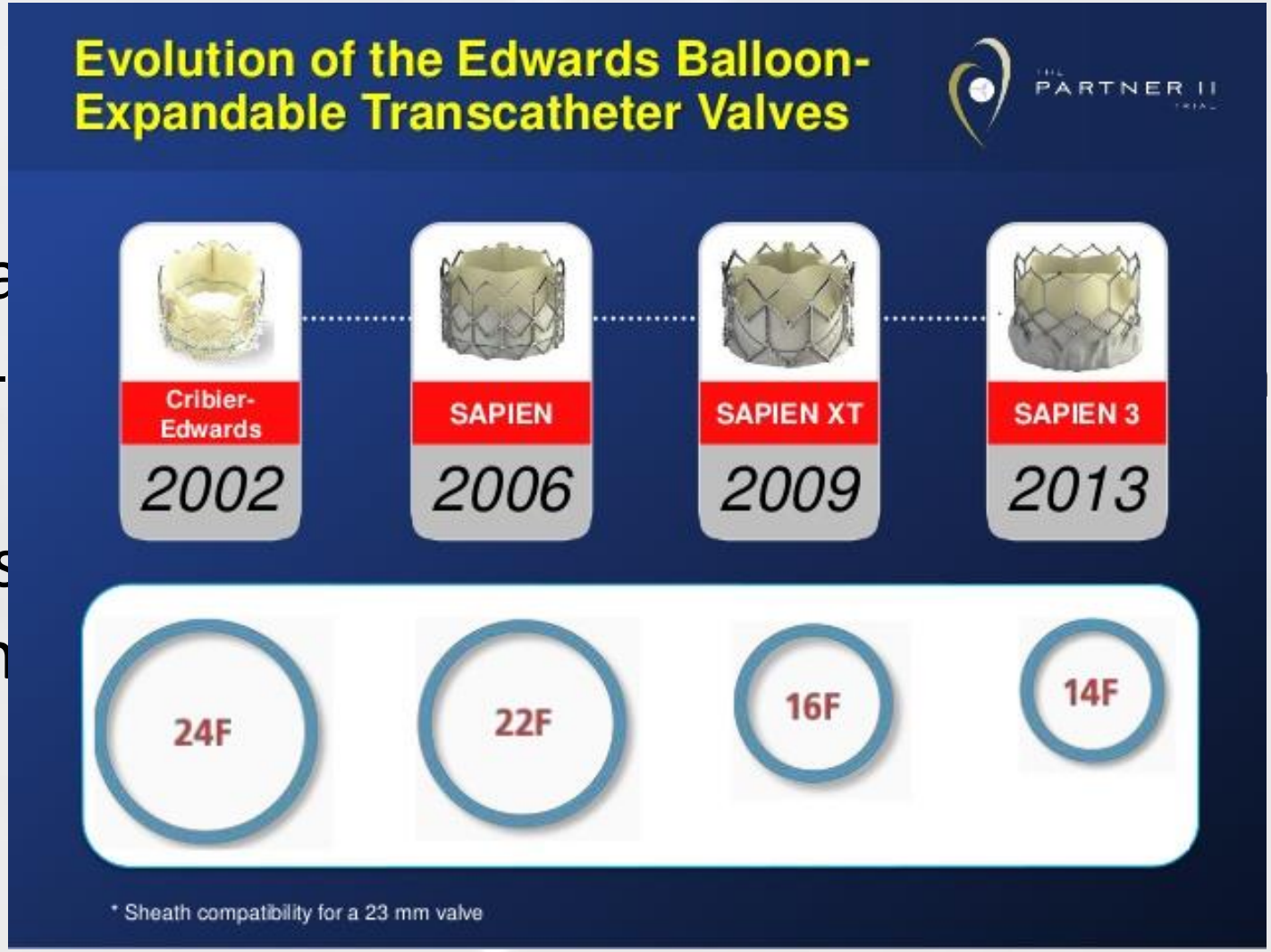
Major Complications:

- Aortic Dissection, Rupture, or Apical Aneurysm
- Access Related Vascular injury leading to death, major bleeding, ischemia, or neurologic impairment.

Minor Complications:

- Access Related Vascular injury leading to minor bleeding.
- Closure device failure

- Pa
  - –
- As
  sh


Evolution of the Edwards Balloon-Expandable Transcatheter Valves
THE PARTNER II TRIAL
Cribier-Edwards
2002
SAPIEN
2006
SAPIEN XT
2009
SAPIEN 3
2013
24F
22F
16F
14F
* Sheath compatibility for a 23 mm valve

tes

Factors Influencing Vascular Complications

- Gender
- Calcification
- PAD
- Sheath Size

IMPACT OF LOW-PROFILE SHEATHS ON VASCULAR COMPLICATION AND BLEEDING DURING TRANSFEMORAL TRANSCATHETER AORTIC VALVE REPLACEMENT

Moderated Poster Contributions
Poster Sessions, Expo North
Monday, March 11, 2013, 9:45 a.m.-10:30 a.m.

Session Title: Structural Heart Disease Intervention
Abstract Category: 49. TCT@ACC-i2: Aortic Valve Disease
Presentation Number: 2114M-227

Authors: *Marco Barbanti, Ronald Binder, Melanie Freeman, David Wood, Jonathon Leipsic, Anson Cheung, Jian Ye, Stefan Toggweiler, John Webb, St Paul's Hospital, University of British Columbia, Vancouver, Canada*

[a]*Genereux et al. J American College of Cardiology; 2014*
[b]*Toggweiler et al. J American College of Cardiology; 2012*
[c]*Barbanti et al. Eurointervention; 2013*

EVMS
Eastern Virginia Medical School
Teaching. Discovering. Caring.™

Local Standard Of Care

- Sentara Heart Hospital
  - High Volume TAVR volume with technical success and complications that are superior to the national average.

- If we can identify patients at risk for peripheral complications we will have a better change of prevention.

Objective

- This study was designed to create an iliac artery morphology score (IMS) to predict major vascular complications and procedural mortality for TAVR.

Methods

Total Valve Replacements N = 341 → Study criteria met N = 198

- July 2011 to July 2015
- Excluded:
  - Transapical access
  - Direct aortic access
  - Subclavian access
  - Inadequate CTA imaging

Outcomes and Analysis

Outcomes	
Overall Complication	12%
Major	3%
Minor	9%
Mortality Rate	3.5%
Average Sheath Size	20 Fr

Factors found to be predictive of major complications in univariate analysis were analyzed in a multivariate model.

Univariate and Multivariate Analysis of Factors Predicting VARC-2 Major Complications				
	Univariate Analysis	Multivariate Analysis		
Variable	Univariate p value	Multivariate p value	Odds Ratio	95% CI
Gender	0.053	0.18	0.269	.024 - 2.9
Sheath Size (mm)	0.053	0.487	1.67	.392- 7.1
SFAR	0.001	0.515	0.515	.001 - 31.7
SEIAR	0.001	0.76	0.76	.001-16.5
Iliac Morphology Score	0.005	0.038	2.8	1.1-7.7
Iliac Calcification	0.001			
Iliac Diameter	0.02			
SFAR = sheath to femoral artery ratio; SEIAR = sheath to external iliac artery ratio				

Iliac Morphology Score

Iliac Anatomic Measurement Grades				
Variable	0	1	2	3
Calcification	none	<25% vessel length	25-50% Vessel Length	>50% of vessel length or any circumferential point
Minimum Diameter (mm)	> 7.1	6.4 < x ≤ 7.1	5.5 < x ≤ 6.4	≤ 5.5

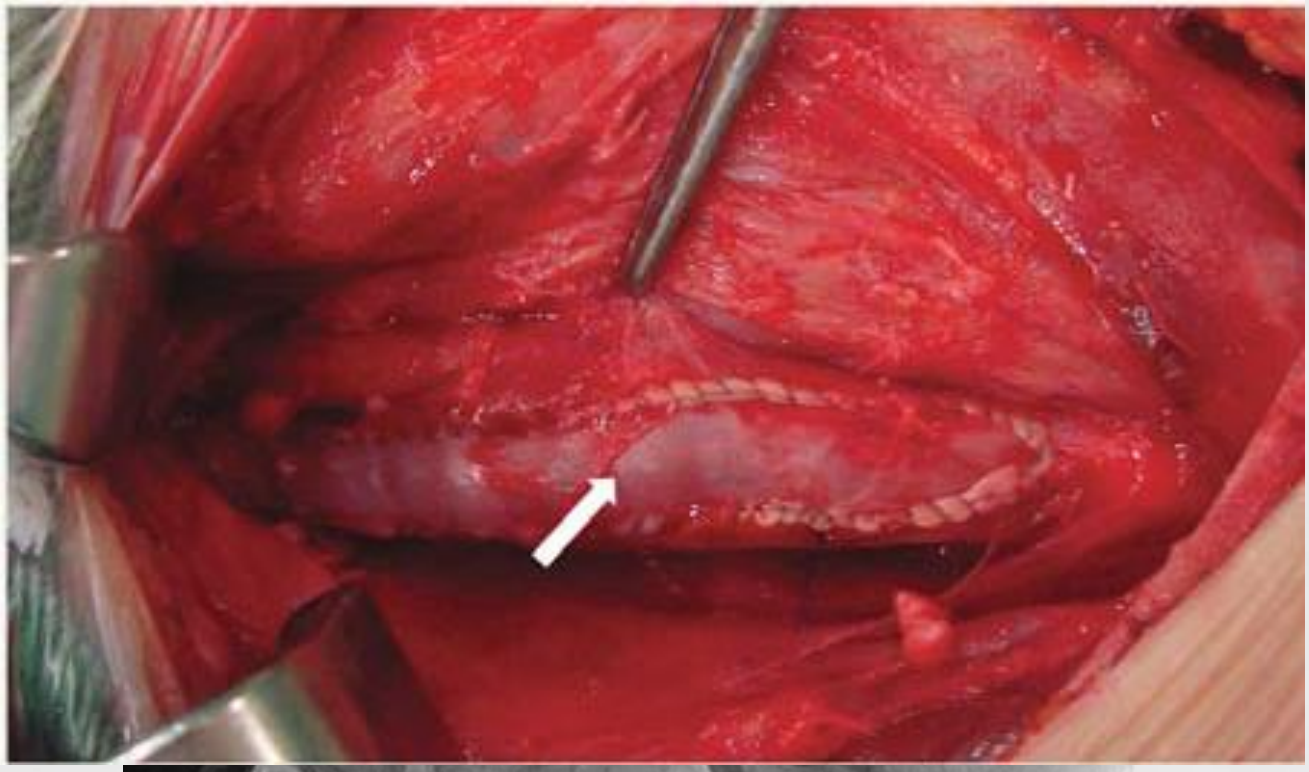
Complication Rates N=198				
Variable	All	Low IMS (N=143)	High IMS (N=55)	p
Major Complications	6 (3%)	1 (.7%)	5 (9%)	0.002
Minor Complications	18 (9%)	13 (9%)	5 (9%)	0.559
Mortality	7 (3.5%)	2 (1.4%)	5 (9%)	0.01

Conclusions

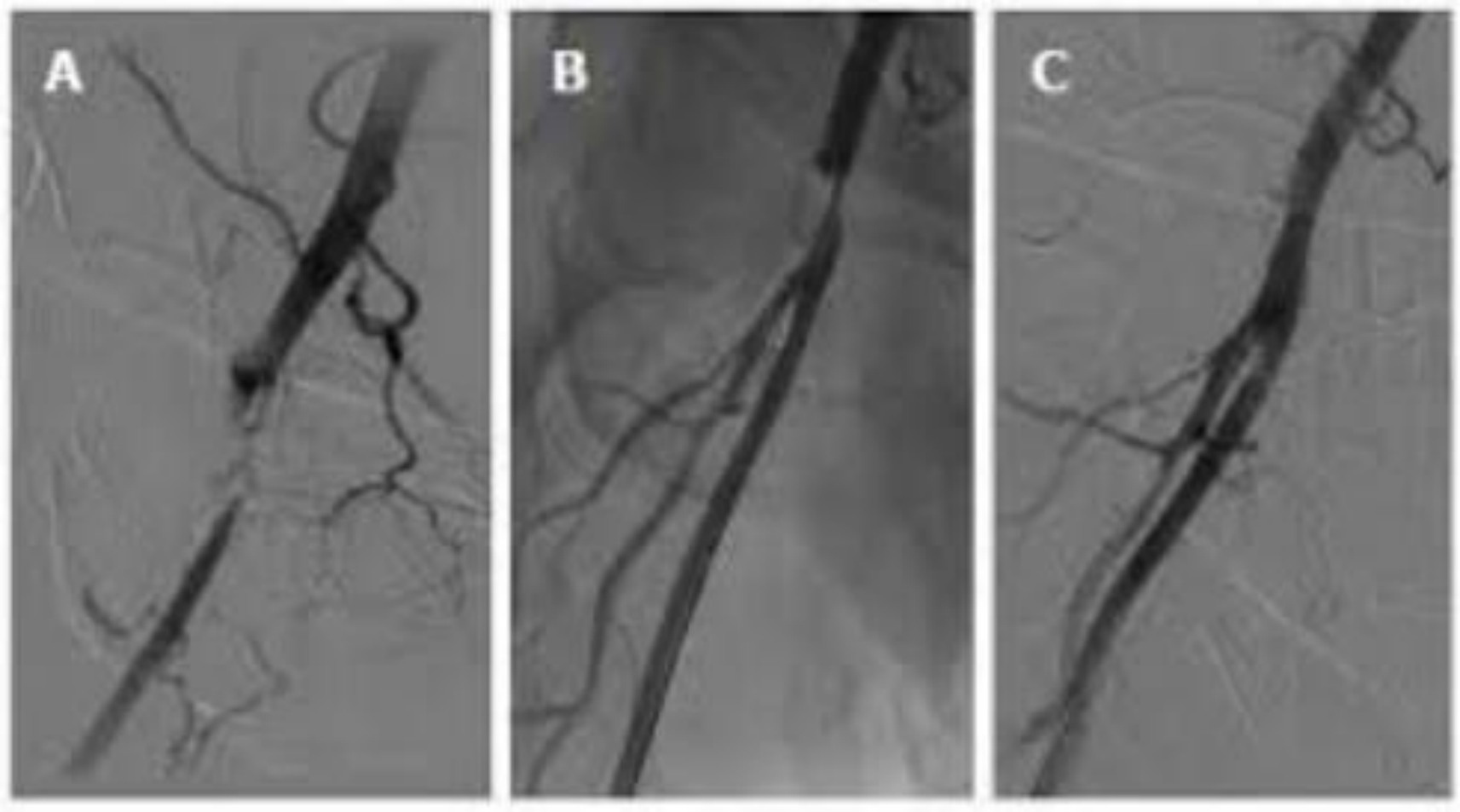
- An IMS composed of ipsilateral minimum iliac diameter plus iliac calcification is an excellent predictor of major vascular complications and mortality.

- Alternative access in patients with high IMS may reduce major vascular complications and procedural mortality.

Repair Options



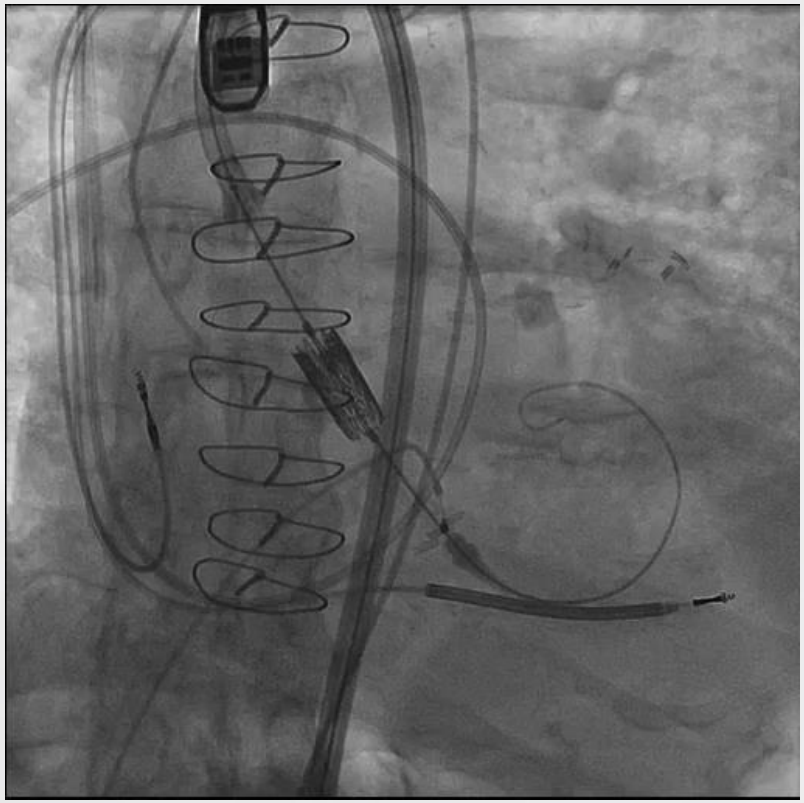
Repair Options



Case study

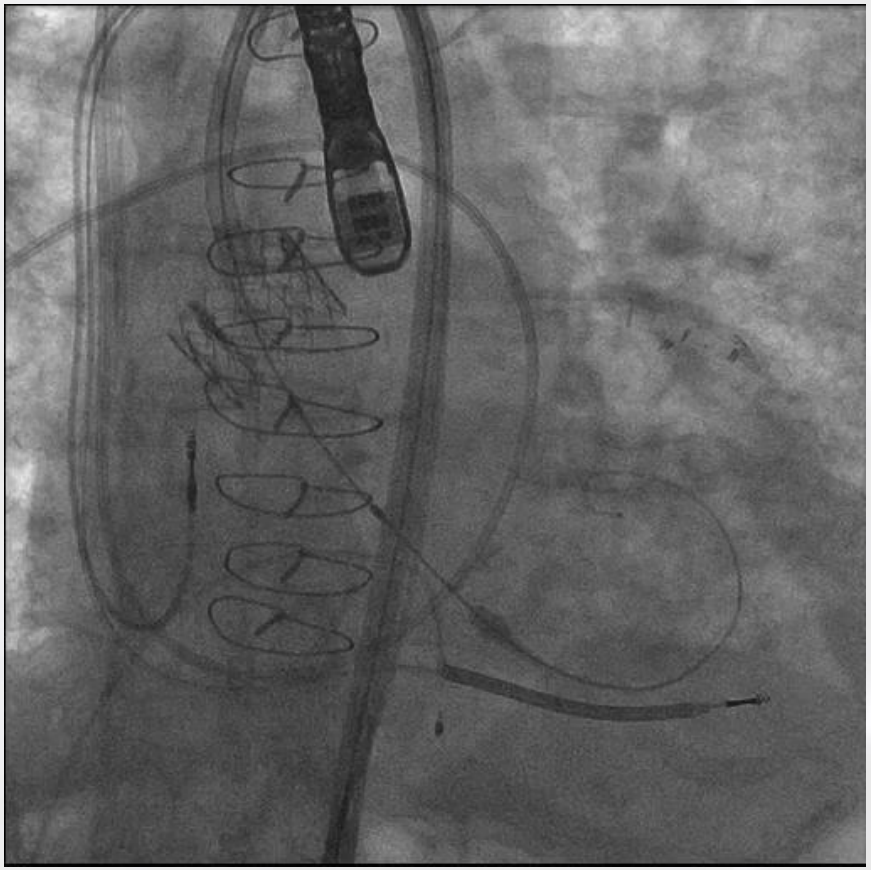
84 year-old Caucasian male presented with SOB, chest pressure, and lightheadedness.

- **Severe symptomatic AS with an AVA of 0.8, EF 20% in an inoperable patient due to multiple co-morbidities and frailty, prior CABG**
- **Transcatheter aortic valve replacement (TAVI) with 26 mm Sapien XT.**



Case study

Embolized Sapiens valve

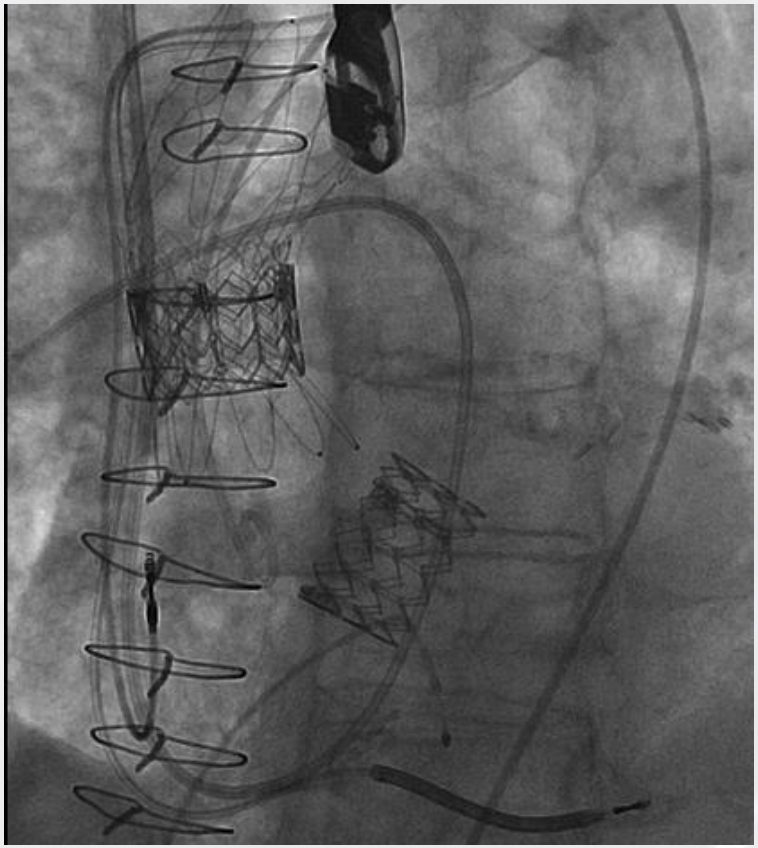


Deployment of a 2nd Sapiens valve

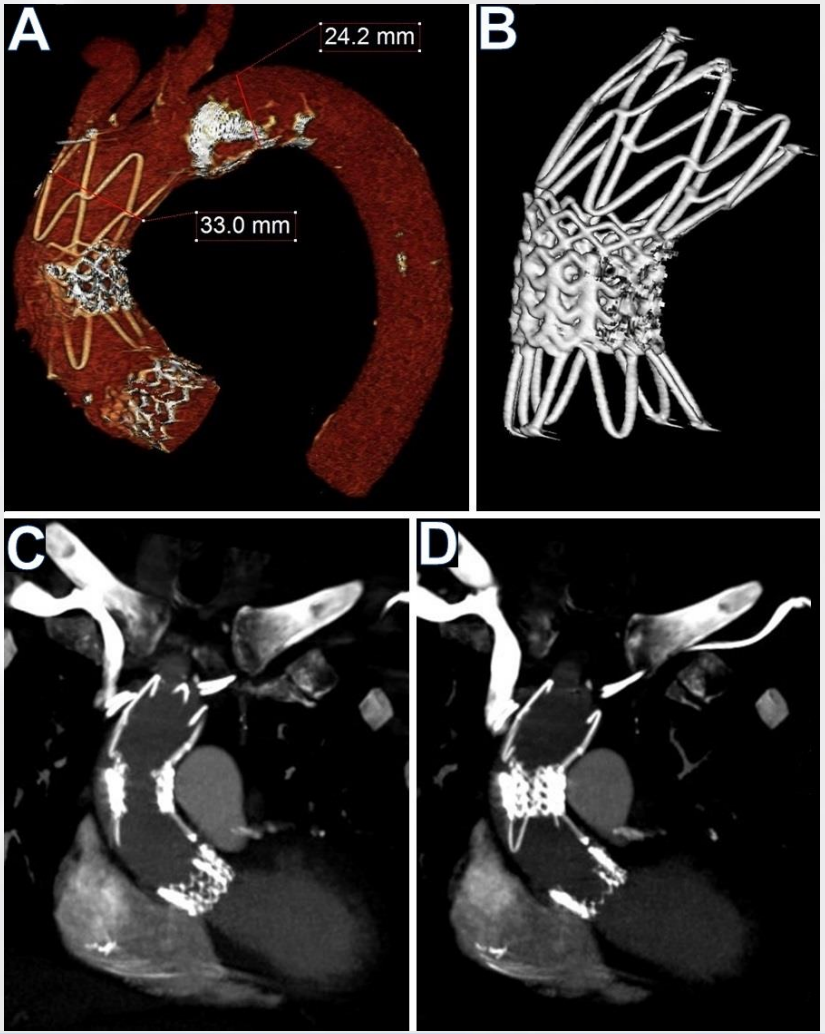
Ascending Devices

Case study

TEVAR rescue with ascending aortic deployment to stabilize the valve



CTA at 1 year



Ascending Devices

Conclusions

- Operating in a hybrid OR with cardiology, cardiac surgery, vascular surgery and high quality imaging has provided excellent technical success and infrequent complications with Sentara's high volume TAVR program