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Which TAVI devices to use: A multi-device patient specific approach

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Eberhard Grube, MD

Physician Name	Company/Relationship
Eberhard Grube, MD	Medtronic, CoreValve: C, SB, AB, OF Direct Flow: C, SB, AB Mitralign: AB, SB, E Boston Scientific: C, SB, AB Biosensors: E, SB, C, AB Kona: AB, E Abbott Vascular: AB InSeal Medical: AB, E, Valtech: E, SB, Claret: SB Keystone: AB Shockwave: E, AB

Key

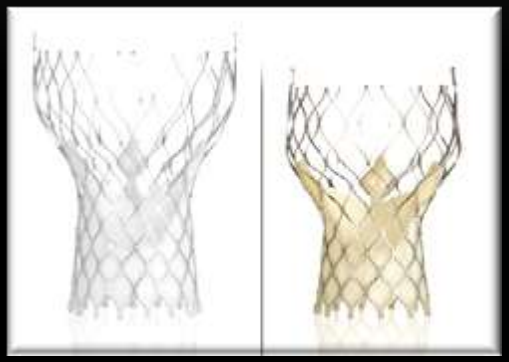
G – Grant and or Research Support E – Equity Interests S – Salary, AB – Advisory Board
C – Consulting fees, Honoraria R – Royalty Income I – Intellectual Property Rights
SB – Speaker's Bureau O – Ownership OF – Other Financial Benefits'

So many TAVR choices…which device is best for which patient?

SAPIEN 3
Edwards

CENTERA EVOLUTION
Edwards

CoreValve & EVOLUT-R
Medtronic



Portico
St. Jude Medical

DirectFlow
DirectFlow Medical

Lotus Valve
Boston Scientific

Symetis Accurate
Valve

Valve medical

What determines Device Choice?

Physician Preference/Experience

Company Relationships

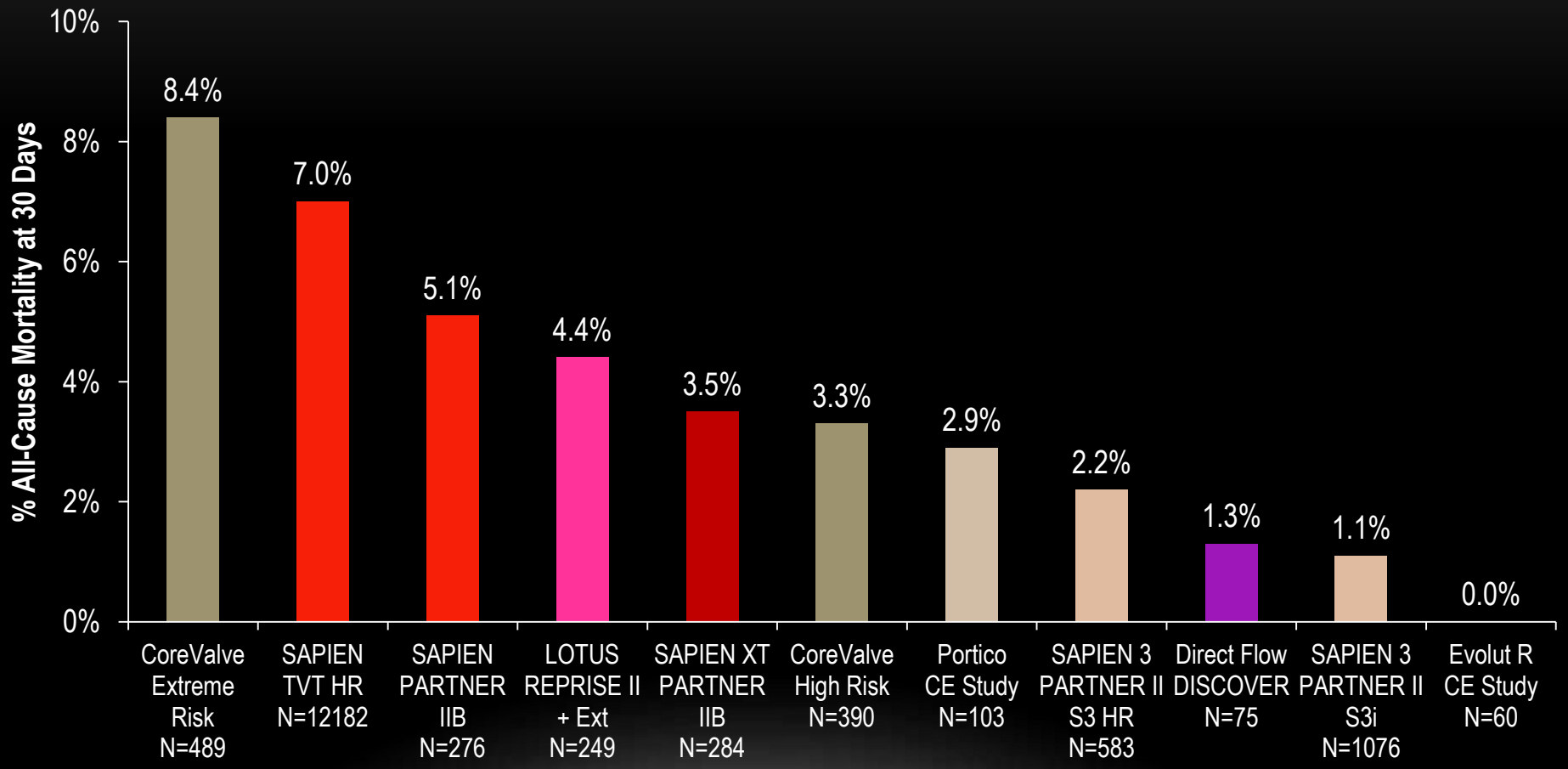
Ease of Use

Patient Anatomy

Reduction of Complications

Mortality is the primary objective for ALL TAVR patients

30 day All Cause Mortality Results



What are the current challenges for TAVR devices?

TAVR Challenges

AR and PVL

Vascular Complications

Conduction Disturbances

Stroke

Patients at risk for PVL, Vascular Complications, & Stroke

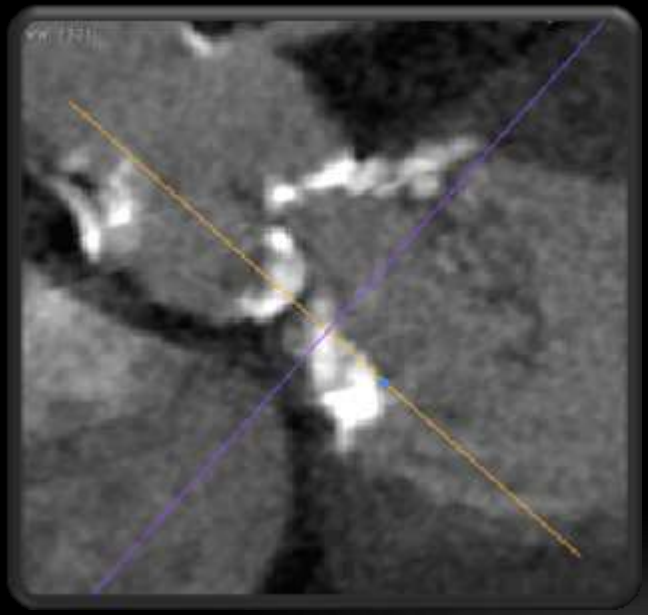
Anatomical Risk Factors

- Highly calcified:
  - Iliac arteries
  - Aorta
  - Femoral arteries
  - Annulus
- Highly tortuous:
  - Iliac arteries
  - Aorta
  - Femoral arteries

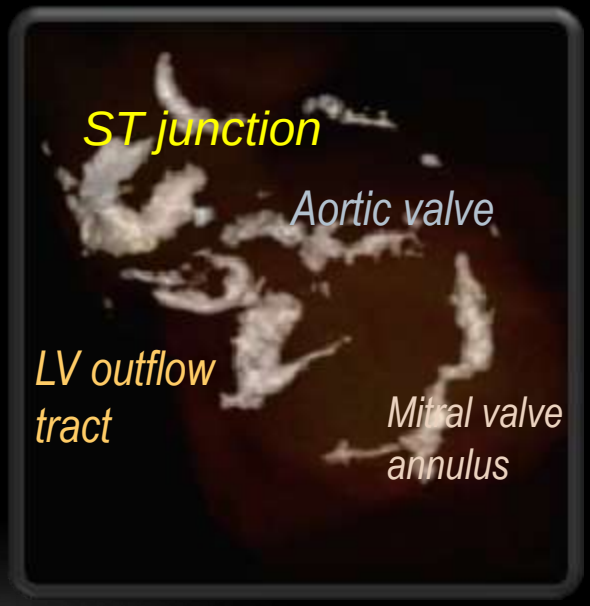
Patients with the above risk factors should be given a device designed to minimize PVL, vascular complication, and stroke

Risk for Patients with significant annular Calcification

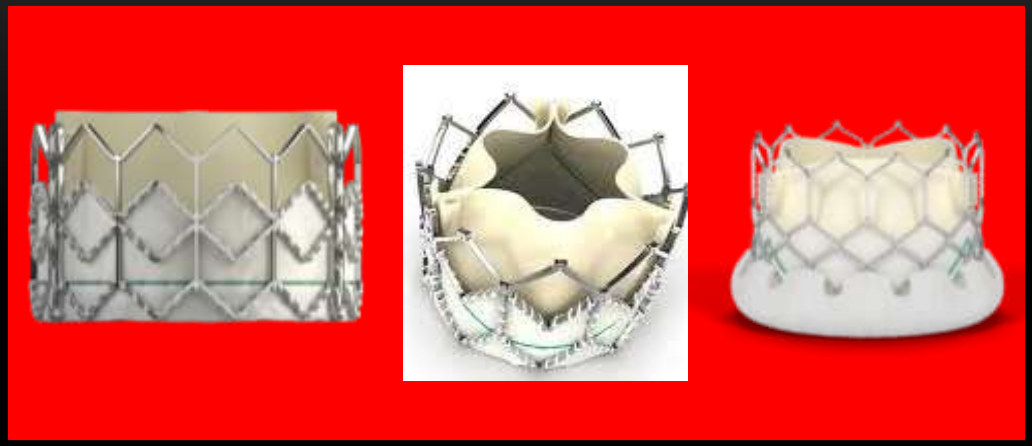
High Risk of Post-Implant Paravalvular Leak



Aortic Root Rupture



Careful with Balloon-Expandable Devices

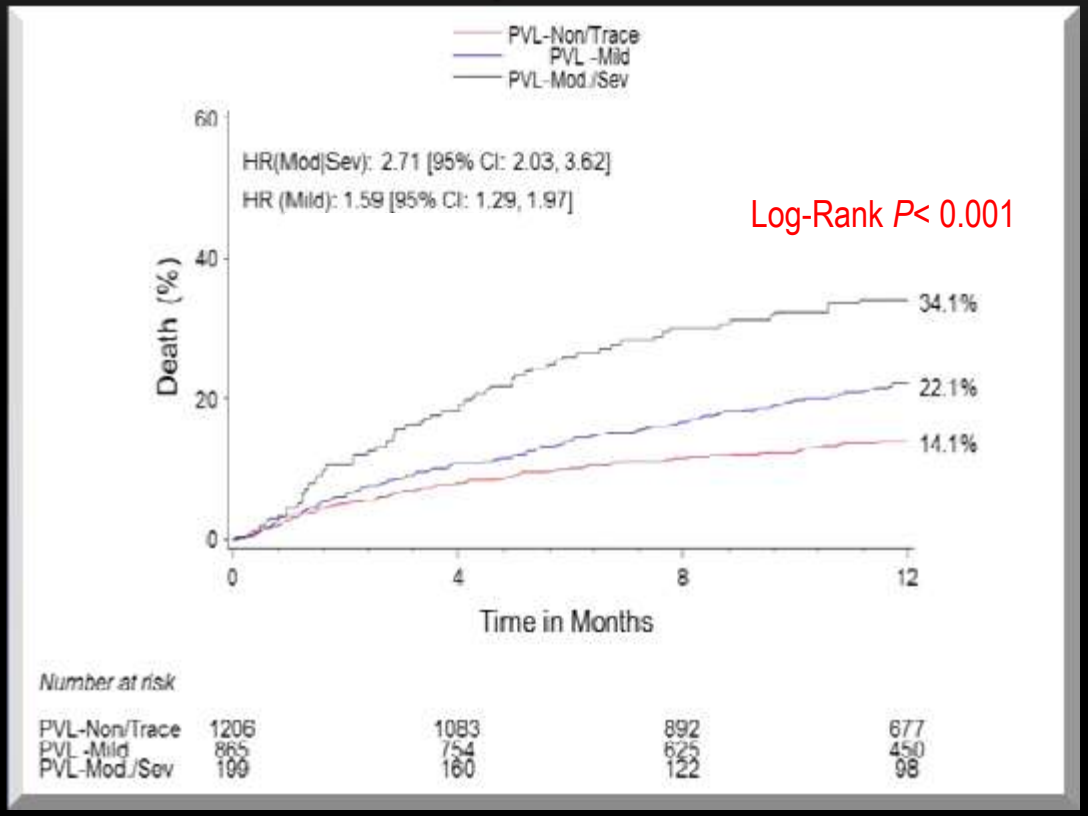


Focus on Self-Expanding, Mechanical Devices

Mortality is the primary objective for ALL TAVR patients

PVL is a Significant Predictor of Mortality

PARTNER Trial 1-Year Outcomes Stratified by PVL



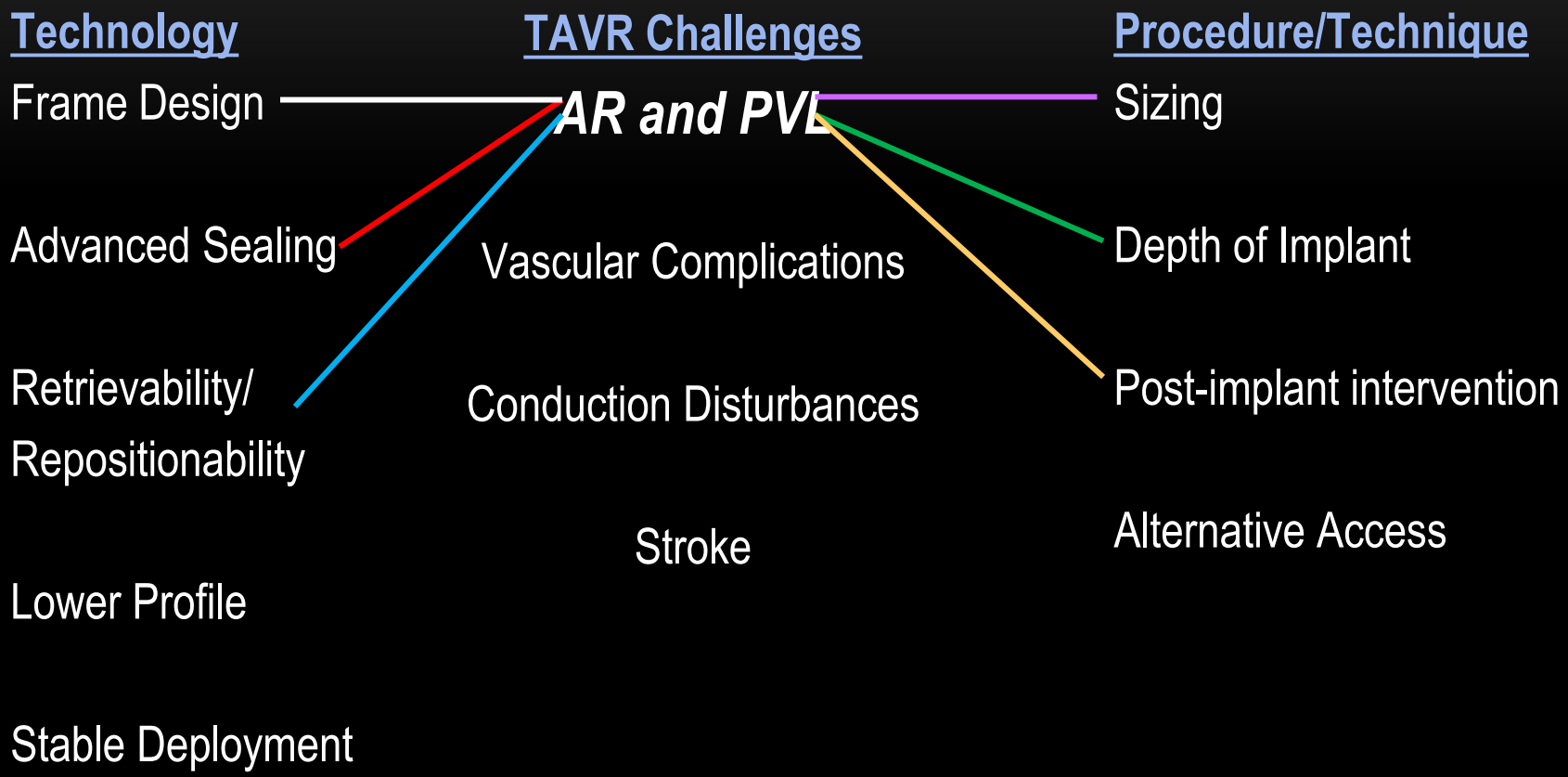
Multivariate Analysis – Predictors of One-Year Mortality

Variable	Hazard Ratio	*P* Value
PVL (Mild vs. None/Trace)	1.47 [1.14, 1.90]	*P*=0.0034
PVL (Mod/Severe vs. None/Trace)	HR=2.38 [1.69, 3.35]	*P*<0.0001

Presented by Suhil Kodali MD at ESC 2013

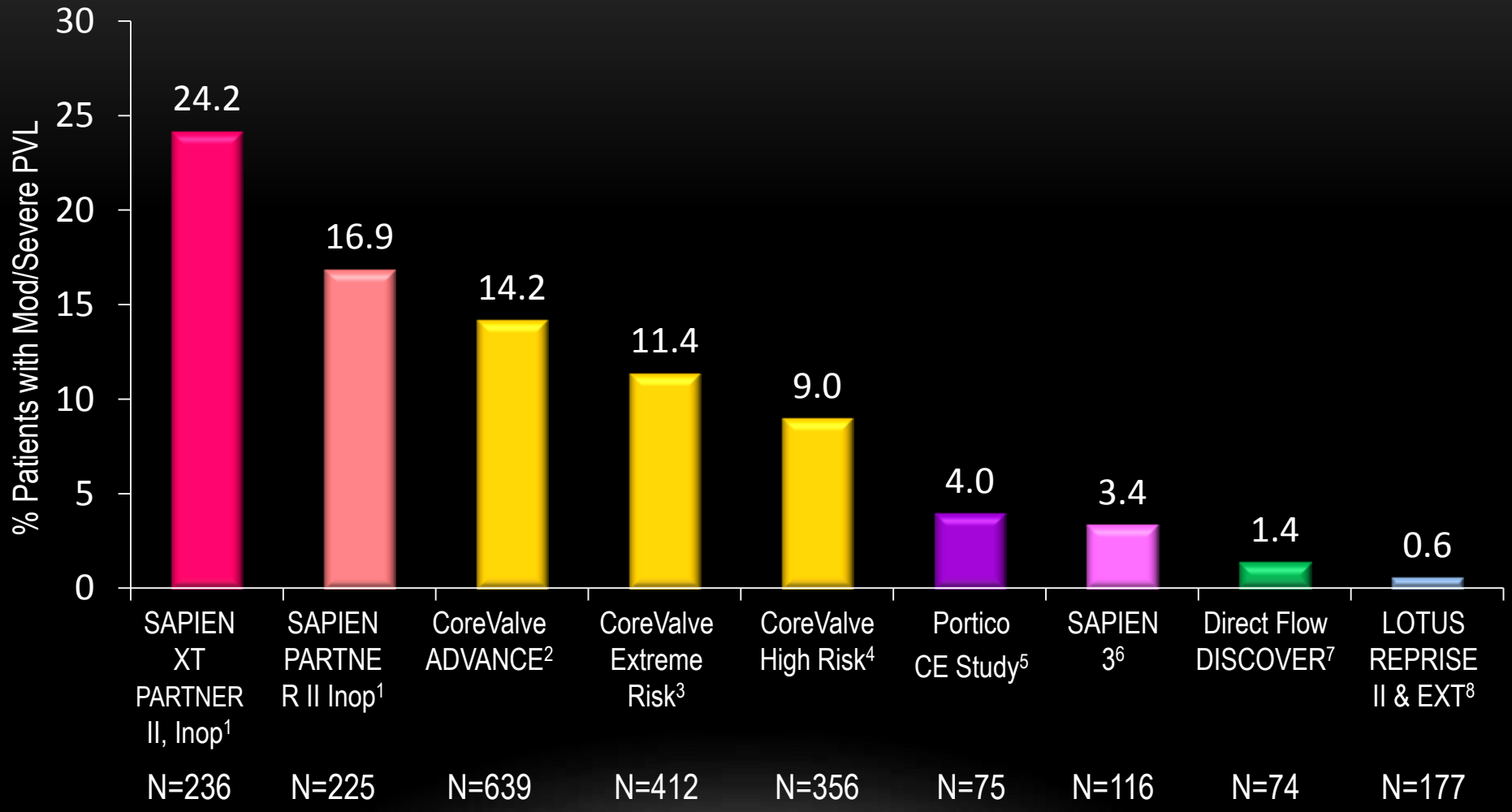
Why are some designs better at reducing PVL?

Understanding how the technology and the technique impact outcomes



Which devices have the lowest PVL?

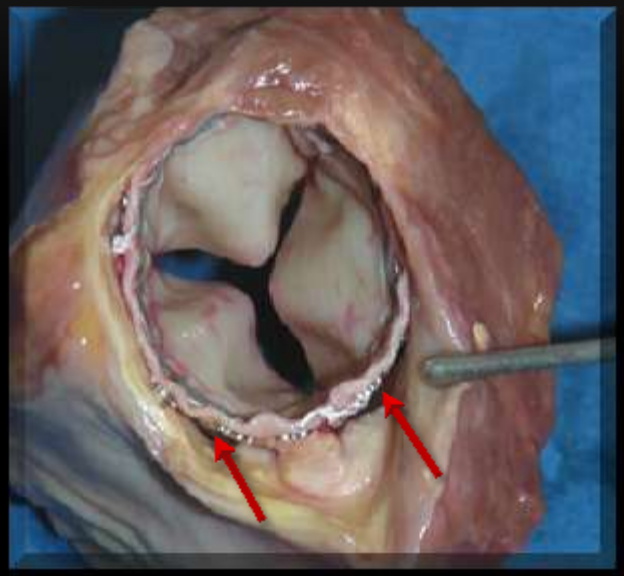
1 Month Moderate & Severe PVL



[1]Leon M, ACC 2013, [2]Linke A, PCR 2014. [3]Popma J, *JACC* 2014; 63(19): 1972-81, [4]Adams D, *N Engl J Med* 2014; 370: 1790-98. [5]Manoharan, et al. TCT 2014. [6]Webb J, EuroPCR 2014. [7]Schofer, JACC 2013. [8]Ian Meredith, London Valves 2014.

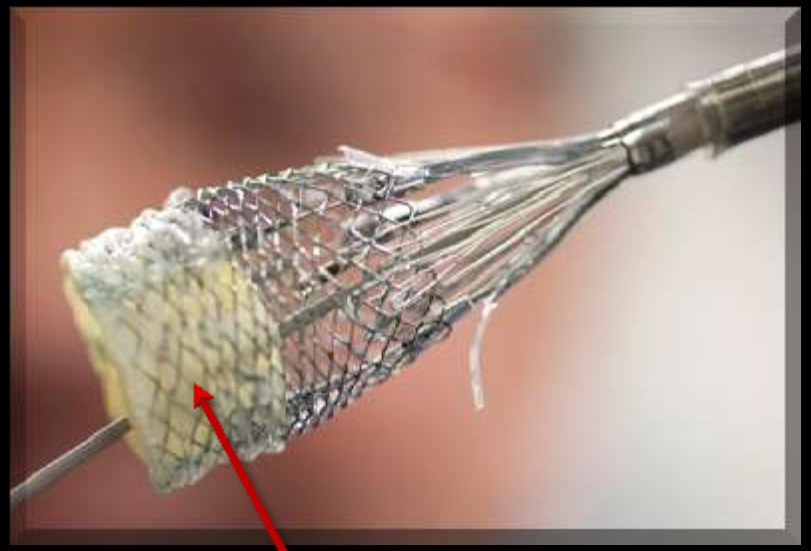
LOTUS VALVE SYSTEM DESIGN GOALS

MINIMIZE PARAVALVULAR LEAKAGE (PVL)



Non – Circular Annulus
+
Irregular Calcification
=
PVL

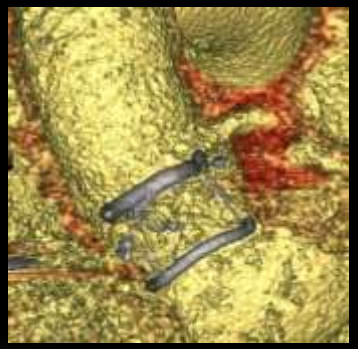
Adaptive seal to mitigate PVL

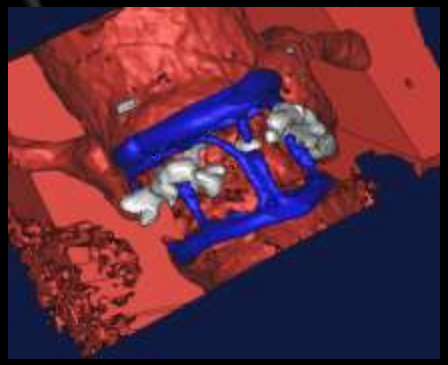


Adaptive
Seal

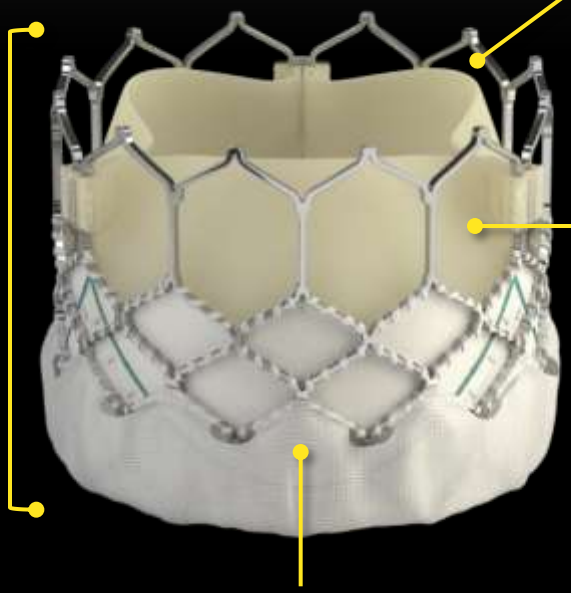
DirectFlow Medical System

- Non-metallic Frame
  - Expandable Dacron polyester double-ring design containing non-compliant PCI technology
  - Tri-leaflet bovine pericardial tissue
- 18Fr delivery and retrieval for all sizes
  - Compatible with 0.035” guidewire
  - 3 positioning wires used for expansion





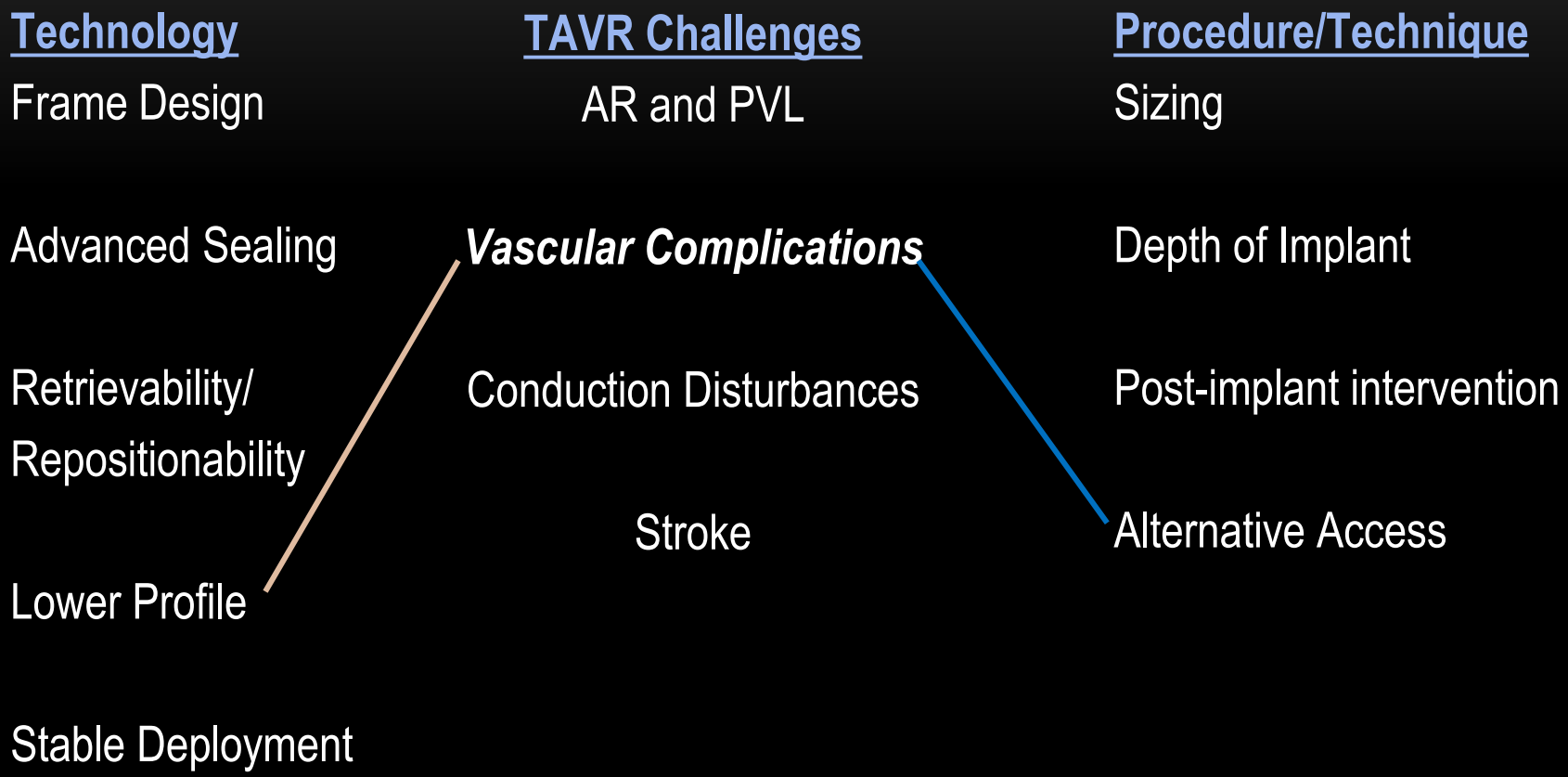
SAPIEN 3



- ✓ Adaptive seal
- ✓ Lower profile valve delivered through a 14 Fr Sheath
- ✓ Treated bovine pericardial tissue

Vascular complications have also been correlated to mortality

Understanding how the technology and the technique impact outcomes



Patient risk for vascular complications – who gets what device

- Risk factors for life-threatening bleedings following TAVR:
  - Female gender
  - Large size delivery system (>19 Fr)
  - Peripheral arterial disease (PVD)
  - Valve retrieval
  - Percutaneous access
  - Highly, tortuous, calcified iliofemoral and aortic vasculature
- Use lowest profile in patients at risk
  - SAPIEN 3 (14Fr)
  - Centera (14Fr)
  - CoreValve Evolut R (14Fr)
  - (Valve Medical (12Fr))
- Opt for approach other than transfemoral

Stroke and TAVR

Understanding how the technology and the technique impact outcomes

Technology

Frame Design

Advanced Sealing

Retrievability/ Repositionability

Lower Profile

Stable Deployment

Embolic Protection

TAVR Challenges

AR and PVL

Vascular Complications

Conduction Disturbances

Stroke

Procedure/Technique

Sizing

Depth of Implant

Post-implant intervention

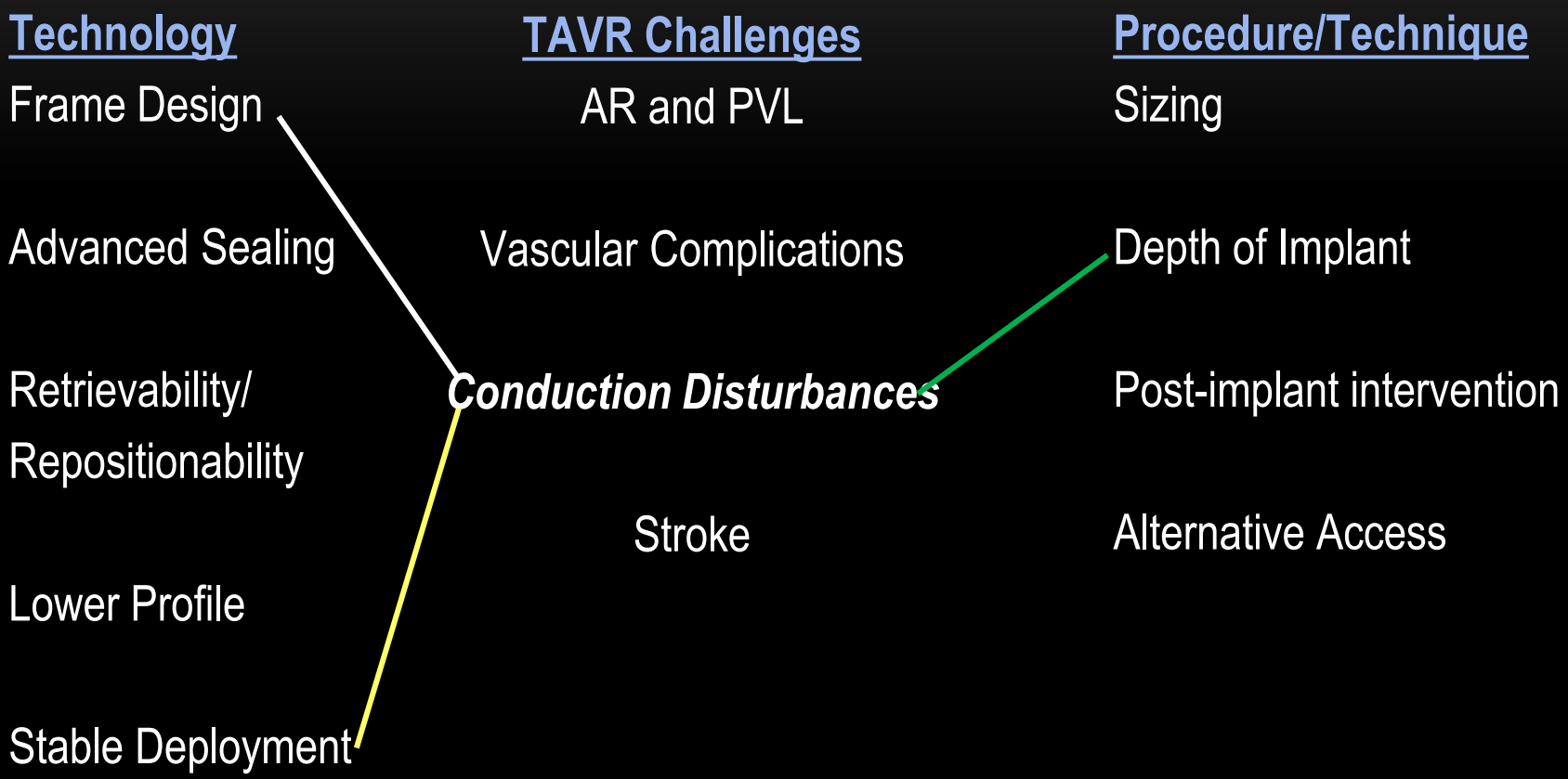
Alternative Access

Anticoagulation Medication

Patients at high risk for stroke should be treated with embolic protection device and medication

Conduction disturbance – Not correlated to mortality

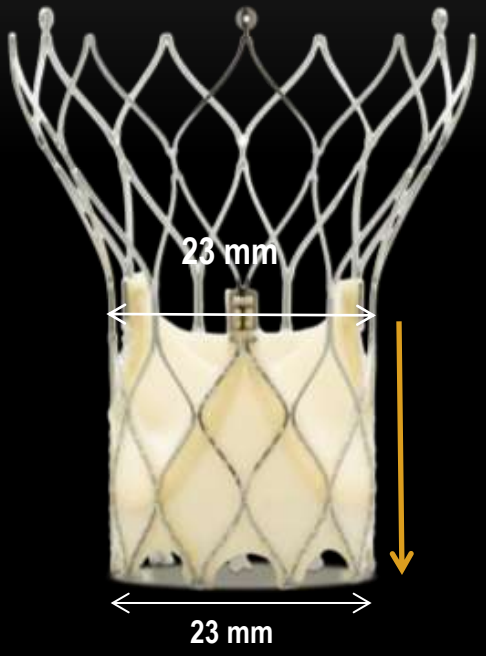
Understanding how the technology and the technique impact outcomes



Patients predictors of conduction disturbance are not well defined. Future studies may further understanding of this current challenge with TAVR devices.

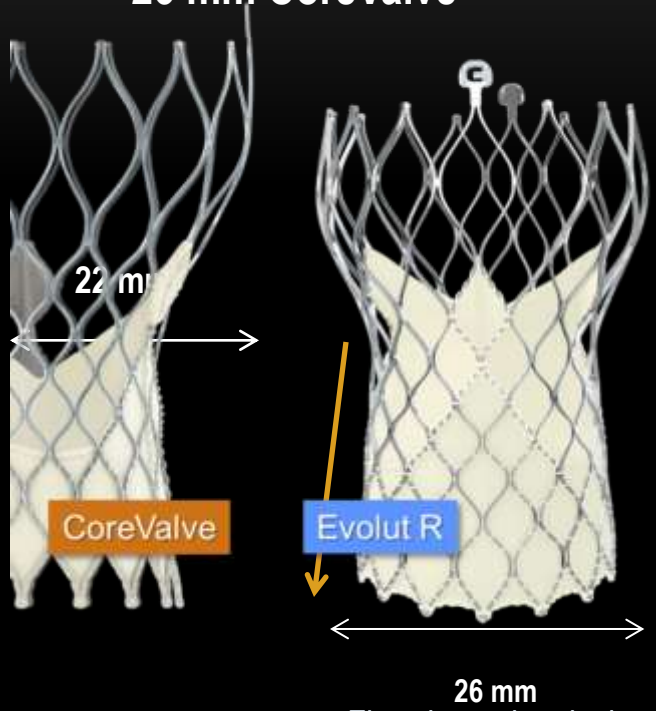
Portico and CoreValve Evolut R designs

23 mm Portico[1]



Non-flared annulus design

26 mm CoreValve[2]



Flared annulus design

Conclusions

- Patients with anatomical risk factors for PVL, vascular complications, and stroke should be given devices with design features to reduce risk
- Mortality is primary objective for all TAVR patients
  - PVL (indicator of mortality)
    - Patients at risk for PVL should possibly receive:
      - Lotus Valve
      - SAPIEN 3
      - DirectFlow
      - CV Evolut R
  - Vascular Complications (linked to mortality)
    - High risk patients should possibly receive devices with lower profile & use alternative access
      - SAPIEN 3 (14Fr)
      - Centera (14Fr)
      - CoreValve Evolut R (14Fr)
  - Risk of stroke can be mitigated with embolic protection device and medication
  - Conduction disturbances are not linked to mortality and patient risk factors unknown