

TCT AP 2013
Seoul, South Korea April , 2013

TAVI

Technology and Procedural Changes

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Eberhard Grube, MD

Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Physician Name

Company/Relationship

Eberhard Grube, MD

Medtronic, CoreValve: C, SB, AB, OF
Sadra Medical: E, C, SB, AB
Direct Flow: C, SB, AB
Mitralign: AB, SB, E
Boston Scientific: C, SB, AB
Biosensors: E, SB, C, AB
Cordis: AB
Abbott Vascular: AB
Capella: SB, C, AB
Valtech: E, SB,
Claret: SB

Key

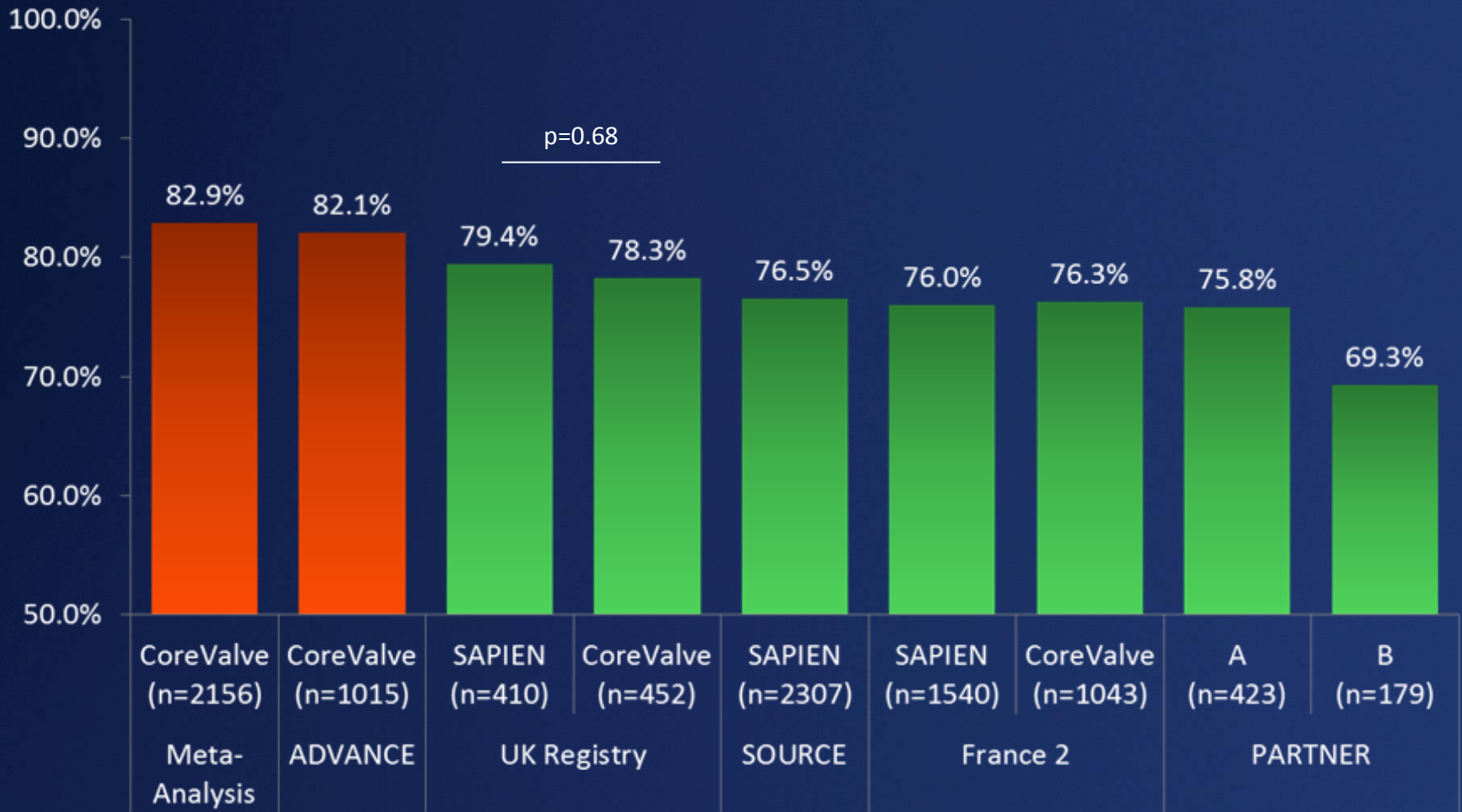
G - Grant and or Research Support E - Equity Interests S - Salary, AB - Advisory Board
C - Consulting fees, Honoraria R - Royalty Income I - Intellectual Property Rights
SB - Speaker's Bureau O - Ownership OF - Other Financial Benefits

Technology and Procedural Changes

- Current State: Positive Overall Therapy Outcomes
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 - Stroke
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 - Vascular complications
 - Conduction disturbances
- Future Innovation
- New Indications

Positive Survival is Being Consistently Achieved

1-Year Mortality



Major Procedural Complications are Rare

CoreValve ADVANCE | Procedural Results

Procedural Parameters	N=996	%
Successful vascular access, delivery & deployment of device & successful retrieval of the delivery system		97.8
Correct position of the device in the proper anatomical location		98.7
Mean aortic valve gradient < 20 mmHg		96.2
No severe AR requiring intervention		97.9
Only one valve implanted in the proper anatomical location		96.0

Major Complications; Valve Related	N=996	%
Annulus Rupture		0.0
Valve Embolization		0.3
Conversion to open AVR		0.1
Coronary Compromised		0.1

Remaining TAVI Challenges

Procedure/Technique

Technology

Stroke

Balloon strategies
Anti-coagulation mgmt

Emboic Protection

AR and PVL

Sizing
Post-implant intervention
(dilation, snare)
Depth of Implant

Frame design
Advanced Sealing
Positioning, Recapture

Vascular
Complications

Alternative Access

Lower profile
Access specific delivery
Coatings

Conduction
Disturbances

Depth of Implant
Balloon strategies

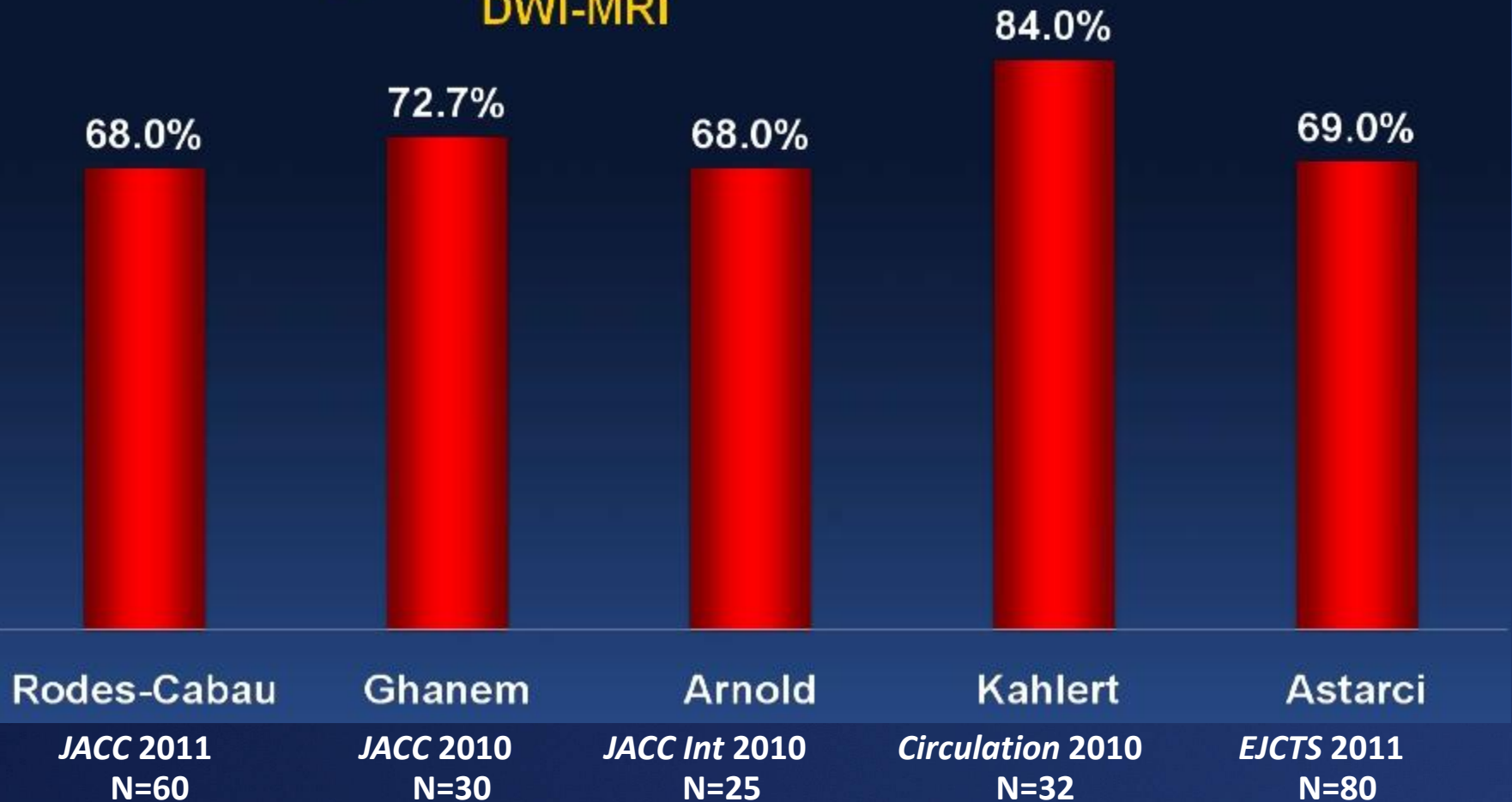
Frame design
Stable deployment
with recapture

Technology and Procedural Changes

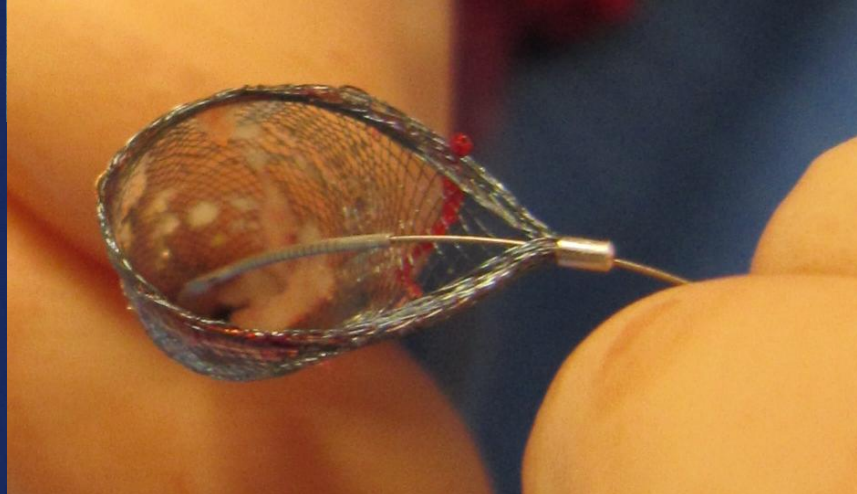
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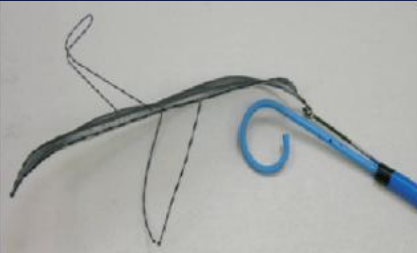
Neuro-Imaging with TAVI

**% of patient with new ischemic lesions on
DWI-MRI**



Embololic Material after TAVI





CEREBRAL DEFLECTION DEVICE

Shimon Embolic protection Filter™
(SMT Research and Development Ltd, Herzliya, Israel)

Positioned in the aortic arch with coverage of the innominate, left carotid and left subclavian artery

Femoral access
8-9 Fr device size
140-micron pore size



CEREBRAL DEFLECTION DEVICE

Umbrella cerebral protection device
(Edwards Lifesciences, Irvine, CA, USA)

Positioned in the aortic arch with coverage of the innominate and left carotid artery

Radial access
6 Fr device size
100-micron pore size



CEREBRAL FILTER DEVICE

Claret CE Pro™ Filter
(Claret Medical Inc., Santa Rosa, CA, USA)

Deployment of two separate filters in the innominate and left carotid artery, respectively

Radial access
6 Fr device size
140-micron pore size



CEREBRAL FILTER DEVICE

Embol-X cerebral protection device
(Edwards Lifesciences, Irvine, CA, USA)

Positioned in the aortic arch

Direct aortic access
24 Fr device size
120-micron pore size

Anti-platelet therapy/anticoagulation in TAVI

Therapeutic Procedure

Intraprocedural therapy:

- Aspirin 500mg
- Clopidogrel 300/75mg
- Heparin

Postprocedural therapy:

- Aspirin 100mg
- Clopidogrel 75mg
- Oral anticoagulation (Afib)

Open Questions

Alternatives???

Aspirin only

Prasugrel/Ticagrelor

Bivalirudine

Duration ???

3 or 6 months

Prasugrel/Ticagrelor

Dabigatran/Rivaroxaban?

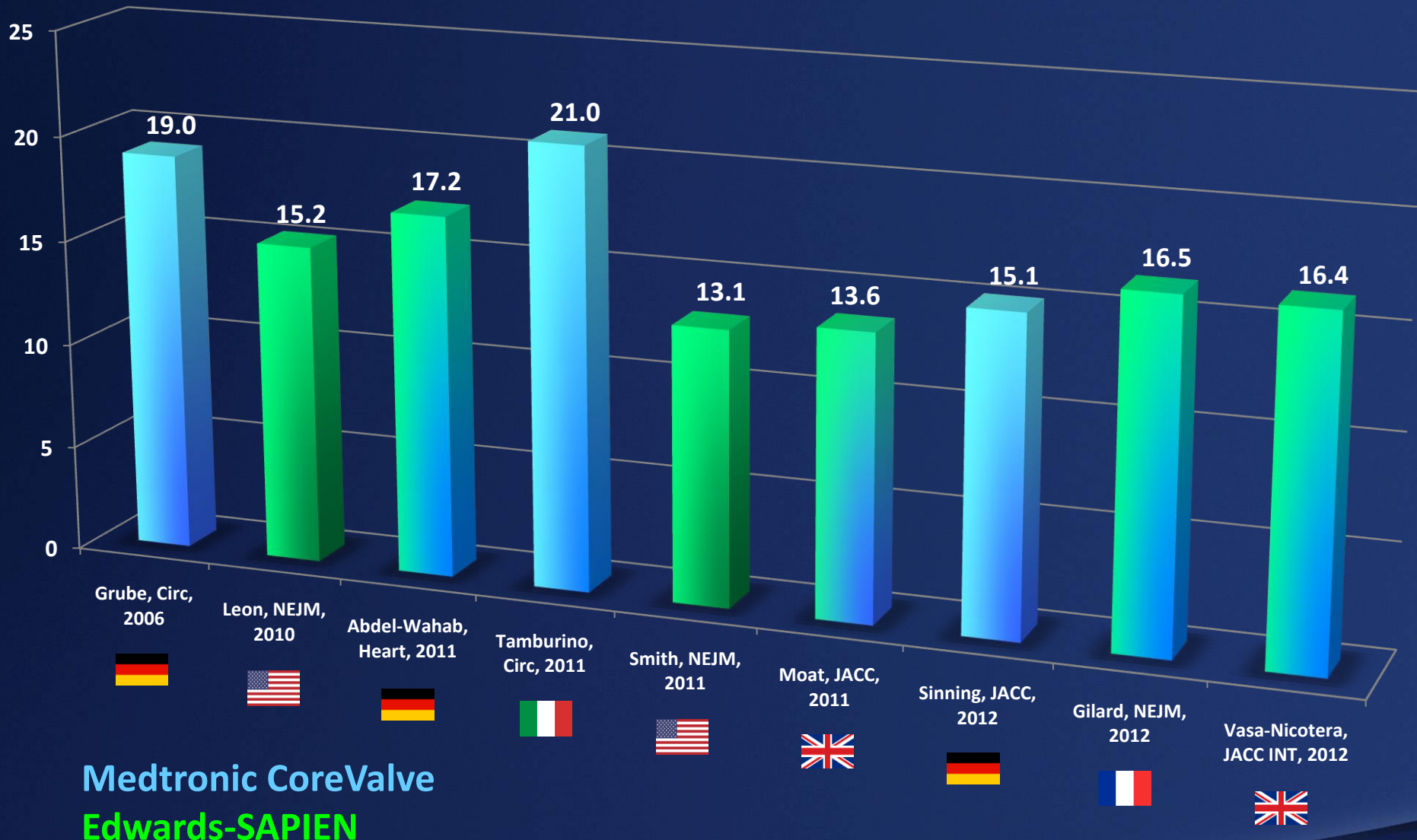
LAA closure in Afib patients?

No evidence-based recommendations!

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Moderate/severe paravalvular AR

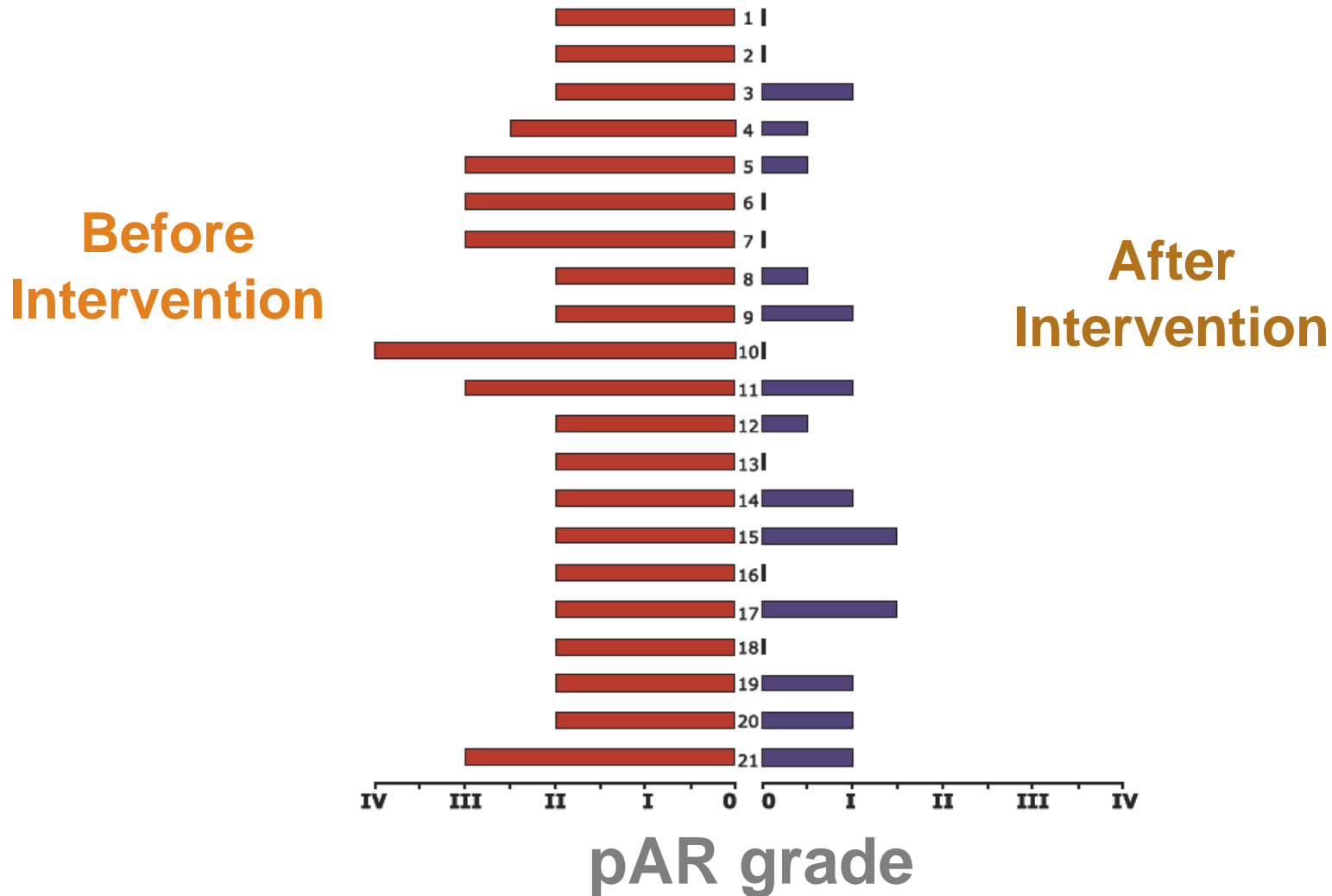


Medtronic CoreValve
Edwards-SAPIEN

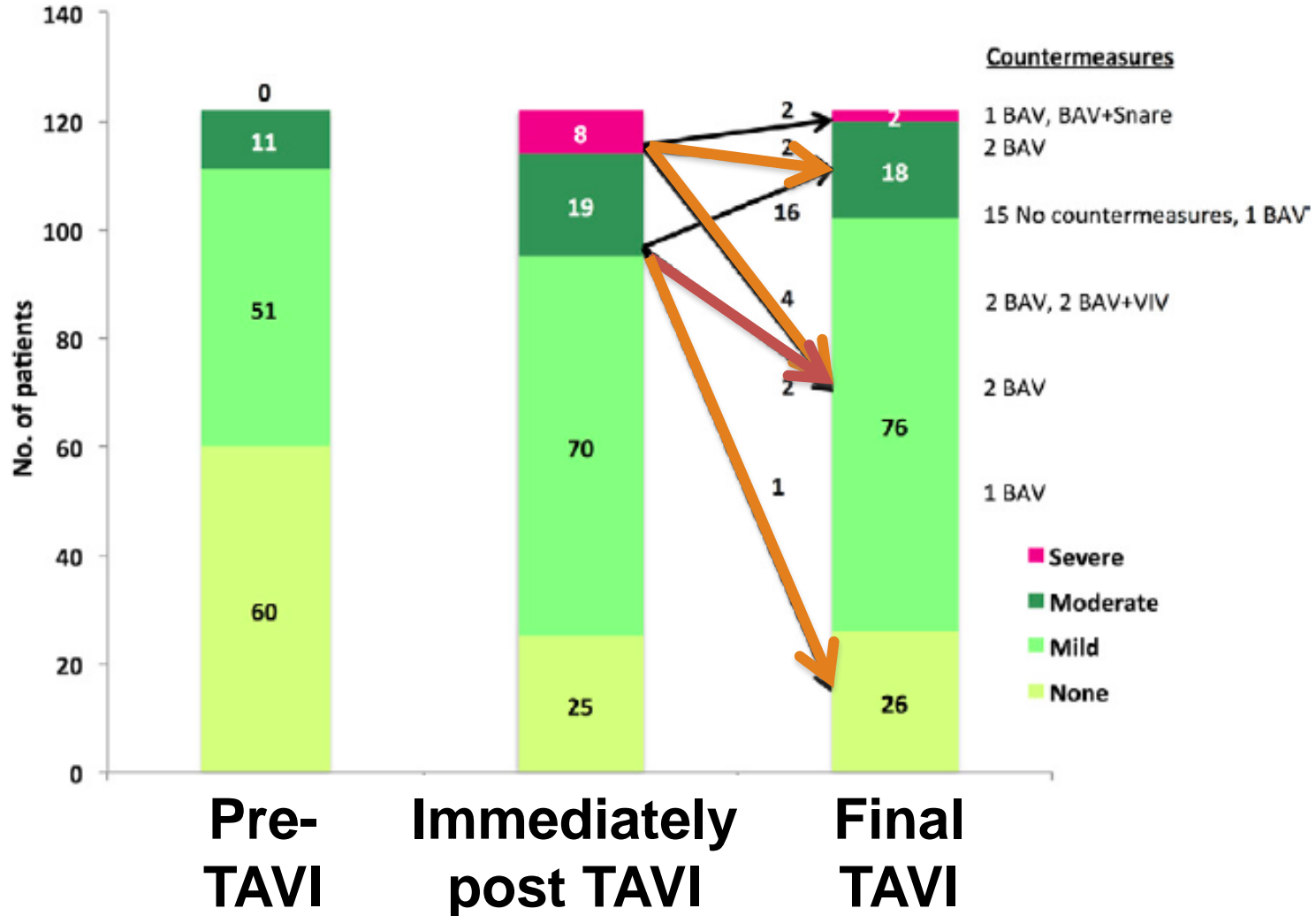
Challenges Remain



Can we improve pAR? (balloon dilation, V-in-V, snare)



Can we improve pAR? (balloon dilation, V-in-V, snare)



New Technologies to Further Reduce PVL

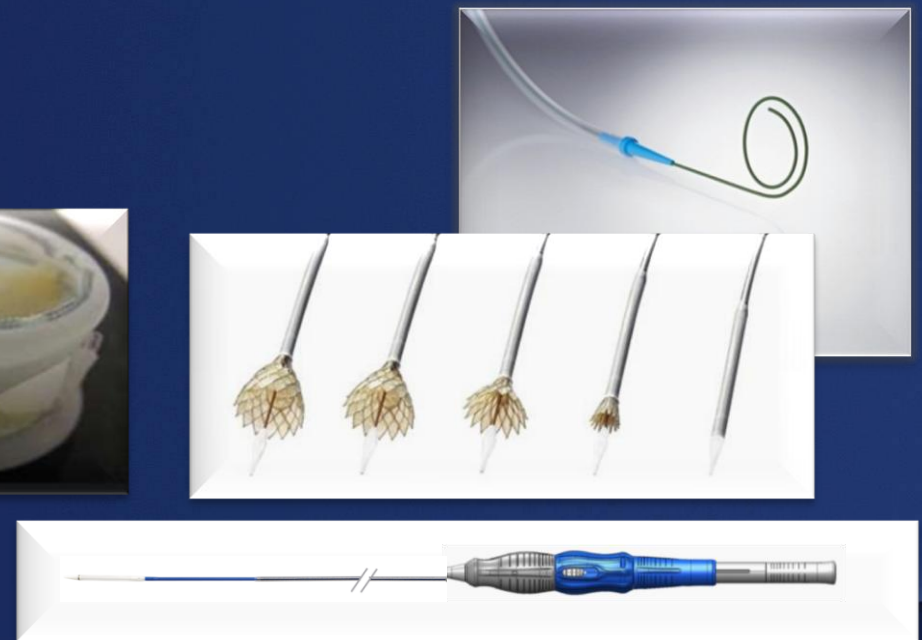
Annular Sealing

- Optimized radial force
- Positioning arms
- Skirt design



Optimal Positioning

- Stable Deployment
- Recapture capability
- Accessories (e.g. guidewire)



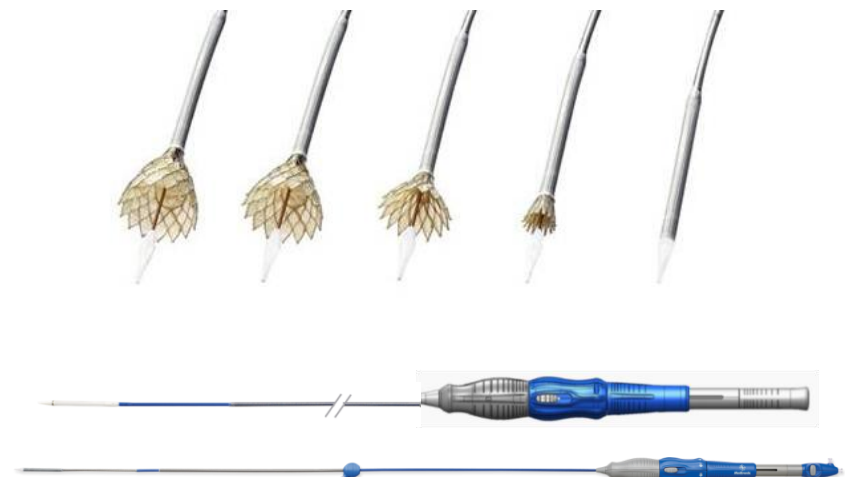
CoreValve Evolut R System with EnVeo R DCS

Fully resheathable, repositionable, recapturable

Evolut R Valve



EnVeo R Delivery System



Ability to recapture across all valve sizes

InLine™ Sheath for 15F delivery profile

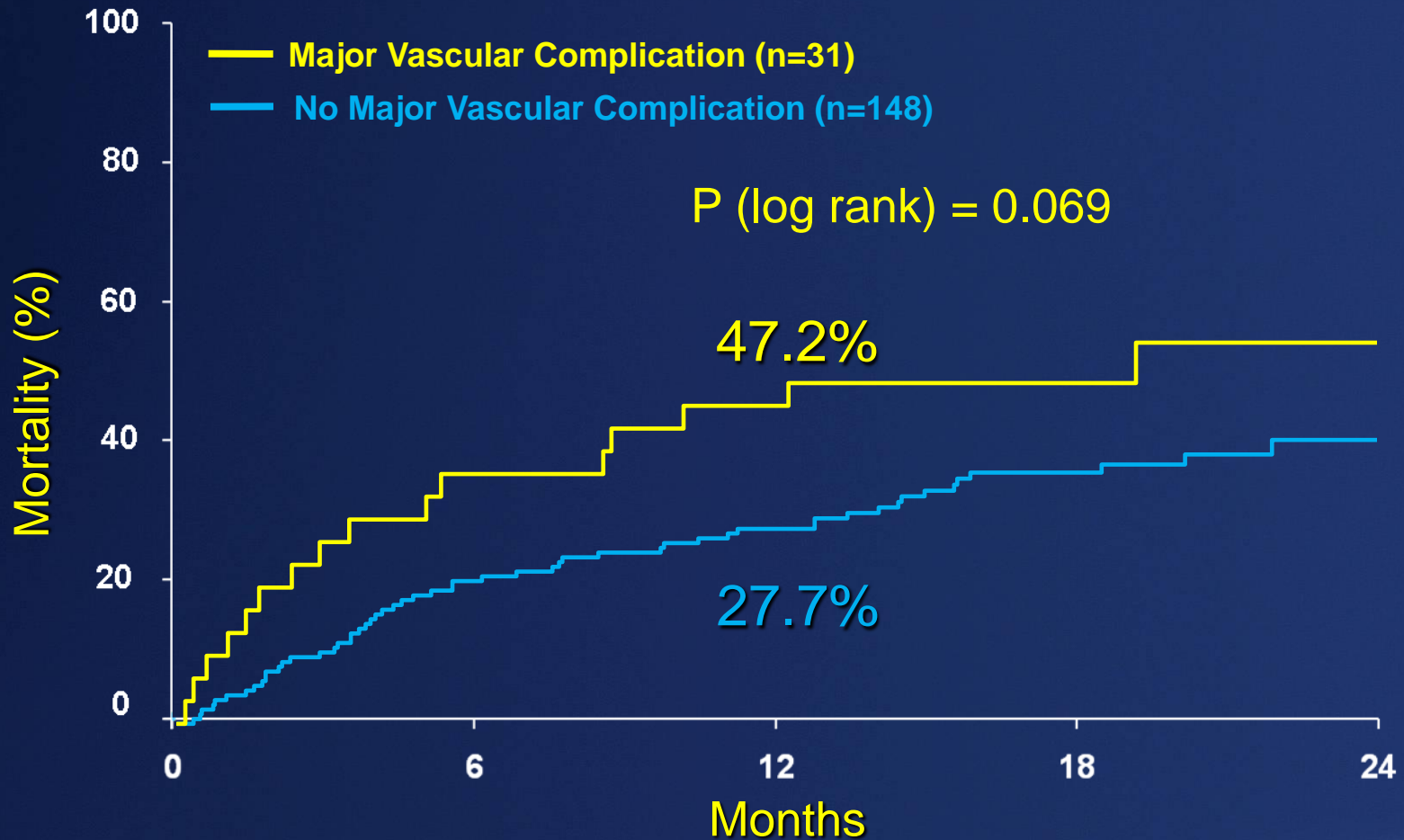
Full annulus range 18-29+ mm

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Mortality and Major Vascular Complications

PARTNER B—TAVI patients



Larger Sheath Size Can Contribute to Major Vascular Complications

A Sheath to Femoral Artery Ratio (SFAR) ≥ 1.05 is a Predictor of both VARC Major Vascular Complications and 30-Day Mortality

Sapien or Sapien XT (n = 102)
CoreValve (n = 28)

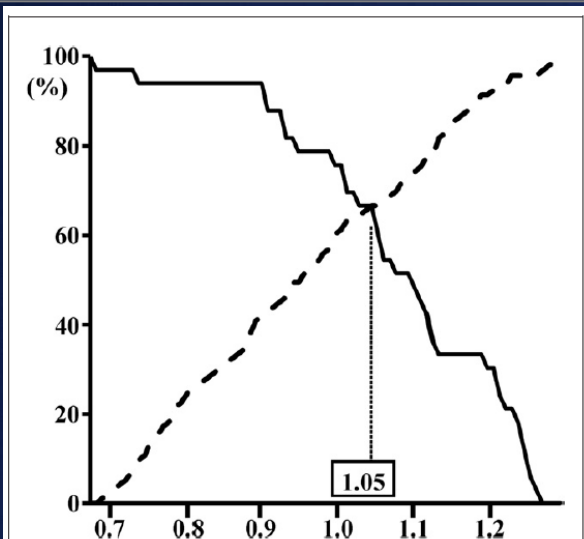


Figure 2. SFAR Threshold Predicts VARC Major Vascular Complications

The sensitivity and specificity curve identified the threshold sheath femoral artery ratio (SFAR) of 1.05 as predictive of VARC major vascular complications. **Solid line** = sensitivity; **broken line** = specificity. VARC = Valve Academic Research Consortium.

Table 6. Comparison of the Clinical Outcomes According to SFAR Threshold

Variables	SFAR		p Value
	≥ 1.05 (n = 55)	< 1.05 (n = 72)	
Any vascular complication	23 (41.8%)	12 (16.7%)	<0.001
VARC Major	17 (30.9%)	5 (6.9%)	0.001
VARC Minor	6 (10.9%)	7 (9.7%)	0.827
Femoral artery complication	15 (27.3%)	9 (12.5%)	0.035
Iliac artery complication	11 (20.0%)	2 (2.8%)	0.002
In-hospital mortality	11 (20.0%)	5 (6.9%)	0.033
30-day mortality	10 (18.2%)	3 (4.2%)	0.016

JACC: CARDIOVASCULAR INTERVENTIONS
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VOL. 4, NO. 8, 2011
ISSN 1936-8798/536.00
DOI: 10.1016/j.jcin.2011.03.019

CVN Interview

Transfemoral Aortic Valve Implantation

New Criteria to Predict Vascular Complications

Kentaro Hayashida, MD, PhD, Thierry Lefèvre, MD, Bernard Chevalier, MD, Thomas Hovasse, MD, Mauro Romano, MD, Philippe Garot, MD, Darren Mylotte, MD, Jhonathan Uribe, MD, Arnaud Farge, MD, Patrick Donzeau-Gouge, MD, Erik Bouvier, MD, Bertrand Cormier, MD, Marie-Claude Morice, MD

Decreased Delivery System Profile to Reduce Major Vascular Complications

InLine™ Sheath Eliminates Need for External Sheath

Sheath-to-femoral artery ratio (SFAR) with the **InLine™ Sheath** is less than 1.00 for all valve sizes (23, 26, 29, and 31mm) in vessels down to 6mm in diameter



Inner Diameter Becomes Effective Delivery Profile, resulting in 15FR delivery profile when using InLine™ Sheath

Current

22 FR (OD)

26.7-29.7FR (OD)



*CoreValve w/ 18Fr
Cook Sheath*



*Sapien XT w/
Edwards Sheath*

Future

18 FR (OD)



*CoreValve Evolut R
w/ InLine Sheath*

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Implant Depth Impacts Conduction Disturbances

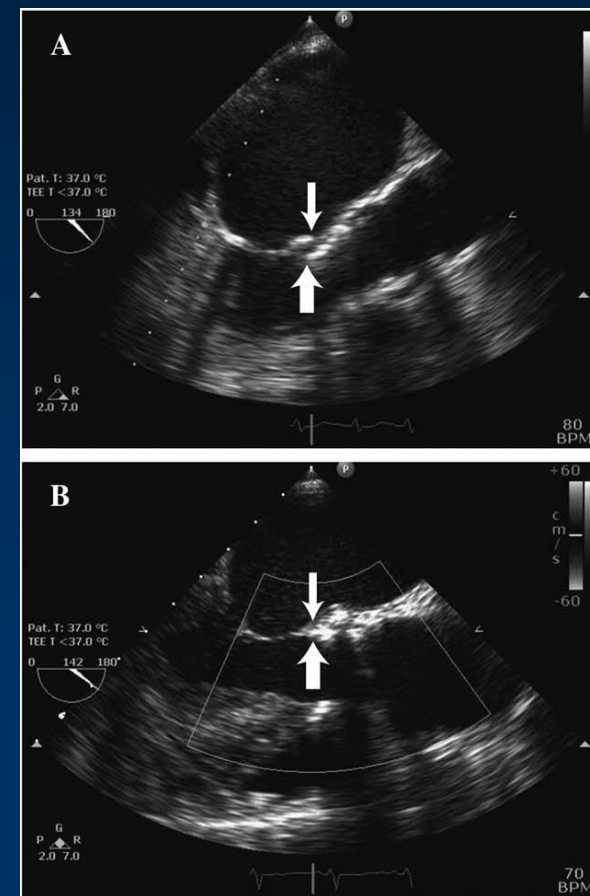
- A lower (ventricular) position of the valve relative to the hinge point of the anterior mitral leaflet was associated with a higher incidence of new LBBB (35% vs. 0%, $P = .029$).

Implanted Above → 0% of patients developed LBBB

Hinge Point of the Anterior Mitral Valve

Implanted Below → 35% of patients developed LBBB

Gutierrez et al. Am Heart J 2009, (N=33)



Feasibility of Transcatheter Aortic Valve Implantation Without Balloon Pre-Dilation

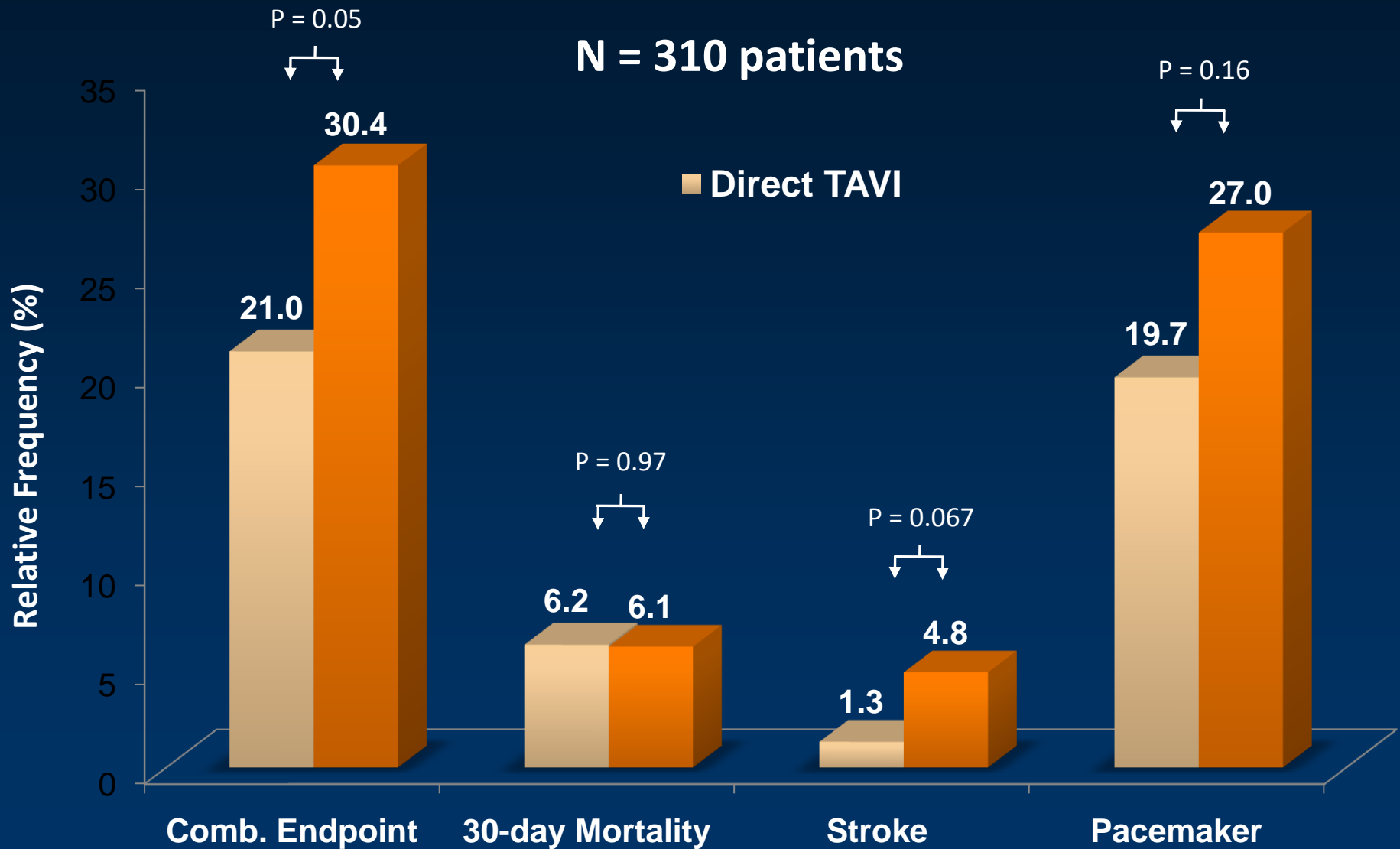
A Pilot Study

Eberhard Grube, MD,* Christoph Naber, MD,† Alexandre Abizaid, MD,‡
Eduardo Sousa, MD,‡ Oscar Mendiz, MD,§ Pedro Lemos, MD,|| Roberto Kalil Filho, MD,||
Jose Mangione, MD,¶ Lutz Buellesfeld, MD#

Bonn and Essen, Germany; Sao Paulo, Brazil; Buenos Aires, Argentina; and Bern, Switzerland

- Pilot study of **60 consecutive patients**
- Procedural success: **96.7%** (58 of 60 patients).
- **A new pacemaker:**
 - **11.7%** (7 of 60) of the patients without balloon pre-dilation
 - 27.8% in a historical control group (n=126)
 - Additionally the **stroke rate was 5%** in patients without balloon pre-dilation as compared to 11.9% in the historical control group.
- TAVI without balloon pre-dilation seems to be feasible and should be investigated further in a larger trial.

Direct TAVI: Bonn-Heidelberg Cohort

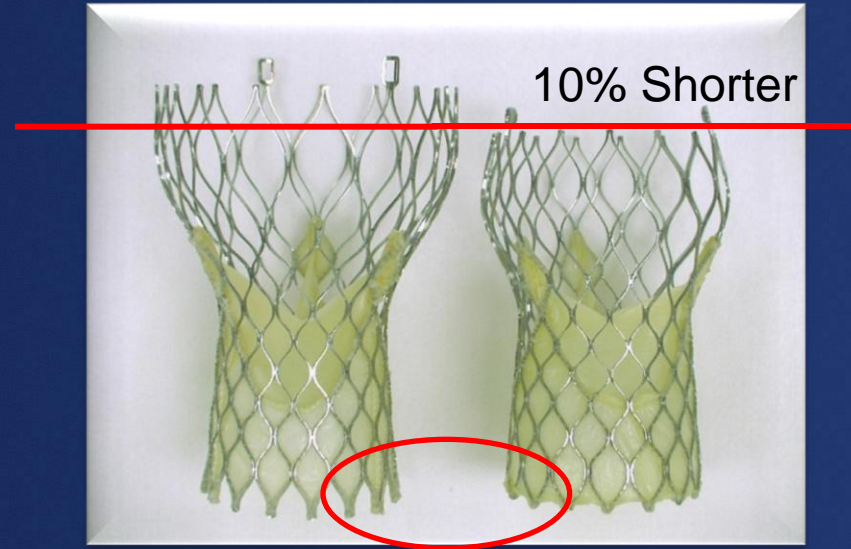


Reducing Post-TAVI Conduction Disturbance

CoreValve Next Generation Systems optimize frame design and provide ability to recapture

CoreValve Evolut frame

- Shorter valve with reduced angulation
- Less traumatic Inflow Crowns



Evolut R with EnVeo R DCS

- Stable, controlled release
- Recapturability



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CoreValve Evolut Innovation Pipeline

Time →

CoreValve Evolut
23 mm
18FR System

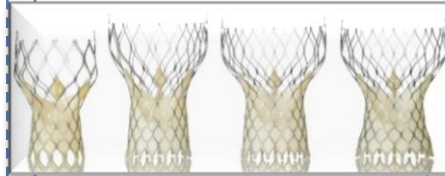


*AccuTrak
Delivery System*

EnVeo
18FR Delivery System



*Compatible with
CoreValve
26/29/31 mm*



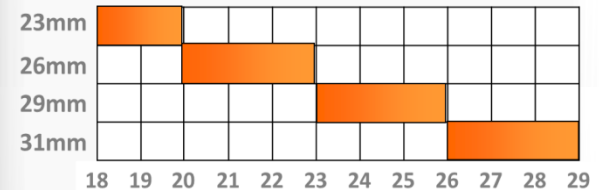
**CoreValve Evolut
Recaptureable
with EnVeo R**
23 mm
15 FR System



**CoreValve Evolut
Recaptureable
with EnVeo R**
26/29/31 mm
15FR System



18 mm to 29 mm Annulus Size Range to
Avoid Patient Prosthesis Mismatch



Patient Annulus Diameter Range (in mm)

Minimizing TAVI Complications: Procedural Solutions

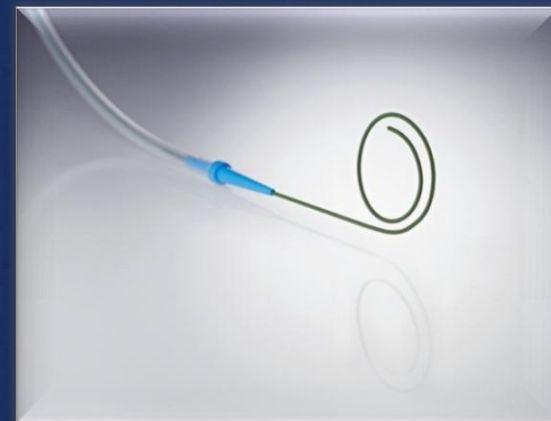
13F Profile Adaptive Sheath

- Nitinol technology – expands and contracts
- Allows navigation of heavily calcified arteries



Pre-Curved Guidewire

- Eliminates need for manual shaping of wire
- Variable wire stiffness throughout for ease of implantation and use

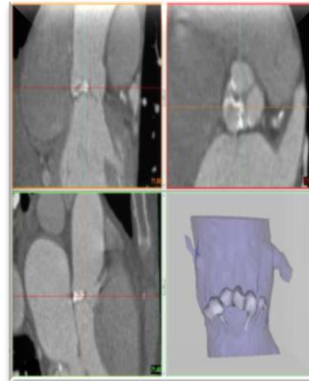


Potential for Expanded Indications

Failed
Bioprosthesis



Pure
Aortic
Insufficiency



Bicuspid
Valve

