TCT Asia-Pacific
Seoul, South Korea

Valve-in-valve TAVI Implantation

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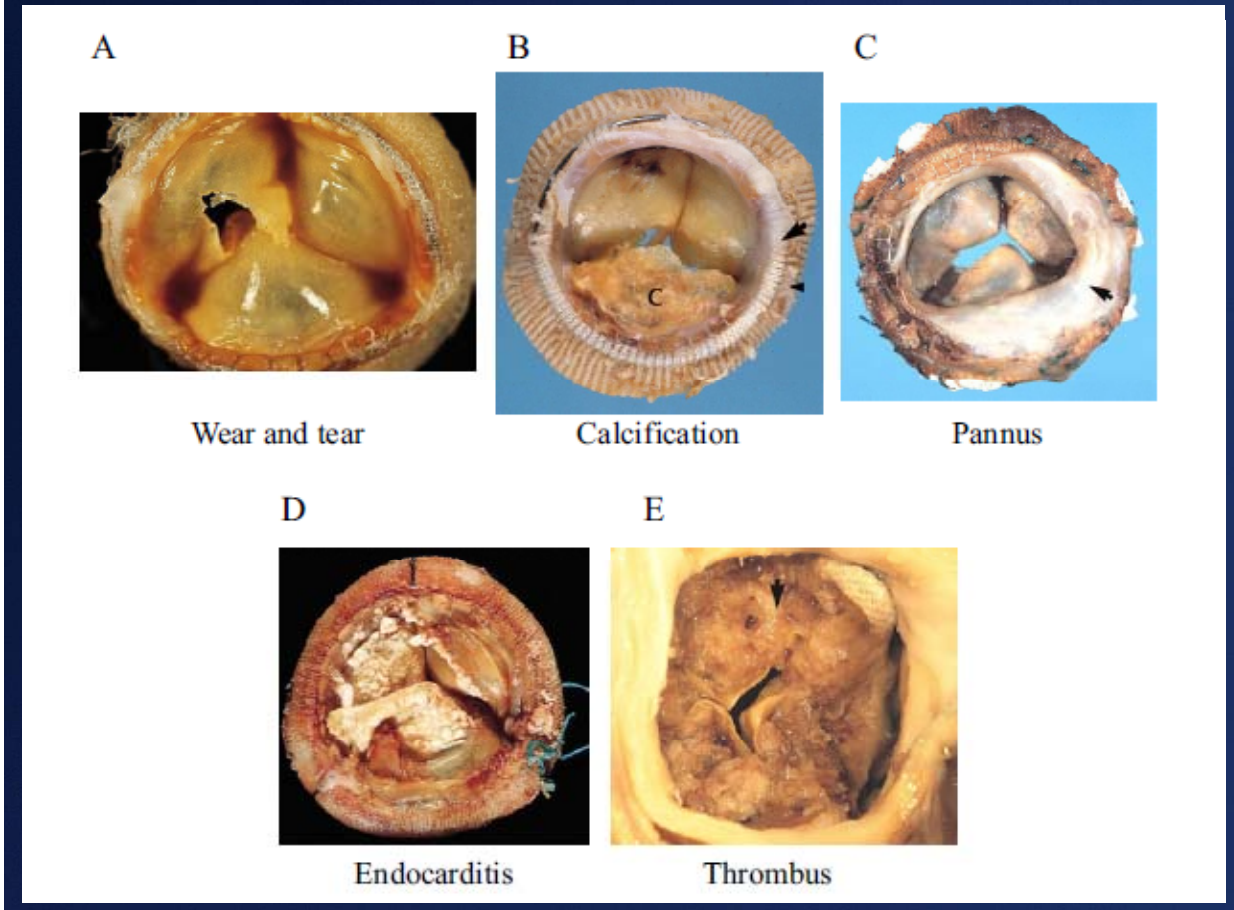
Why Valve-in-Valve?

- Growing need for treatment options for patients with failed bioprosthetic valve as population ages, life expectancy improves, and use of bioprosthetic valves increases
- Operative mortality for elective redo aortic valve surgery is generally low (2% to 7%) , but it can increase to more than 30% in high-risk and non-elective patients
- Because transcatheter aortic valve (TAV)-in-surgical aortic valve (SAV) implantation represents a minimally invasive alternative to conventional redo surgery, it may prove to be safer and just as effective as redo surgery
- Prospective comparisons with a large number of patients and long-term follow-up are required to confirm these potential advantages

1. Piazza, N, et al. *JACC Cardio Interventions*. 2011;4:721-32.

Most Common Reasons for Bioprosthetic Valve Failure [1]



(A) Wear and tear

(B) Calcific degeneration

(C) Pannus

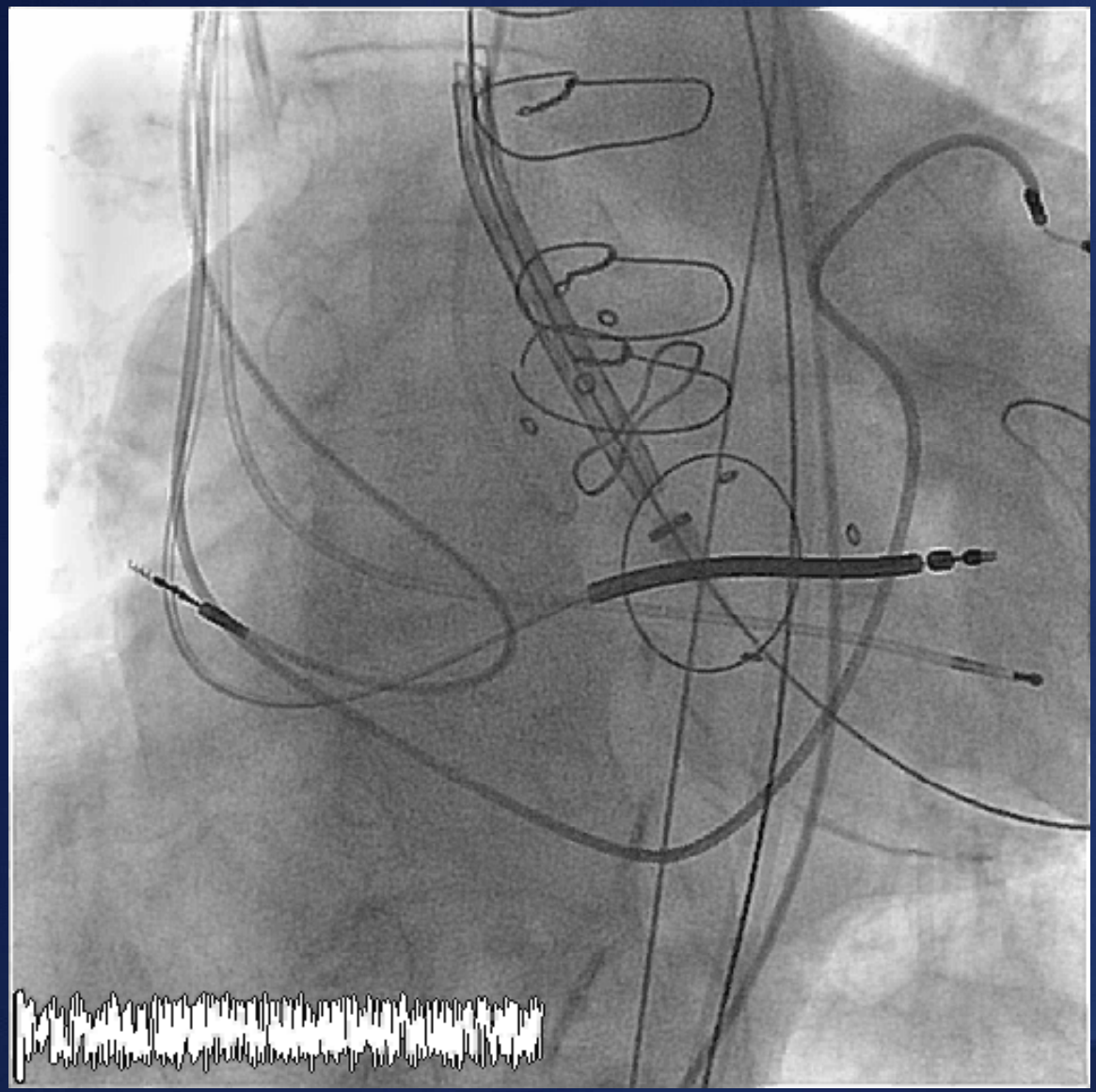
(D) Endocarditis

(E) Thrombus

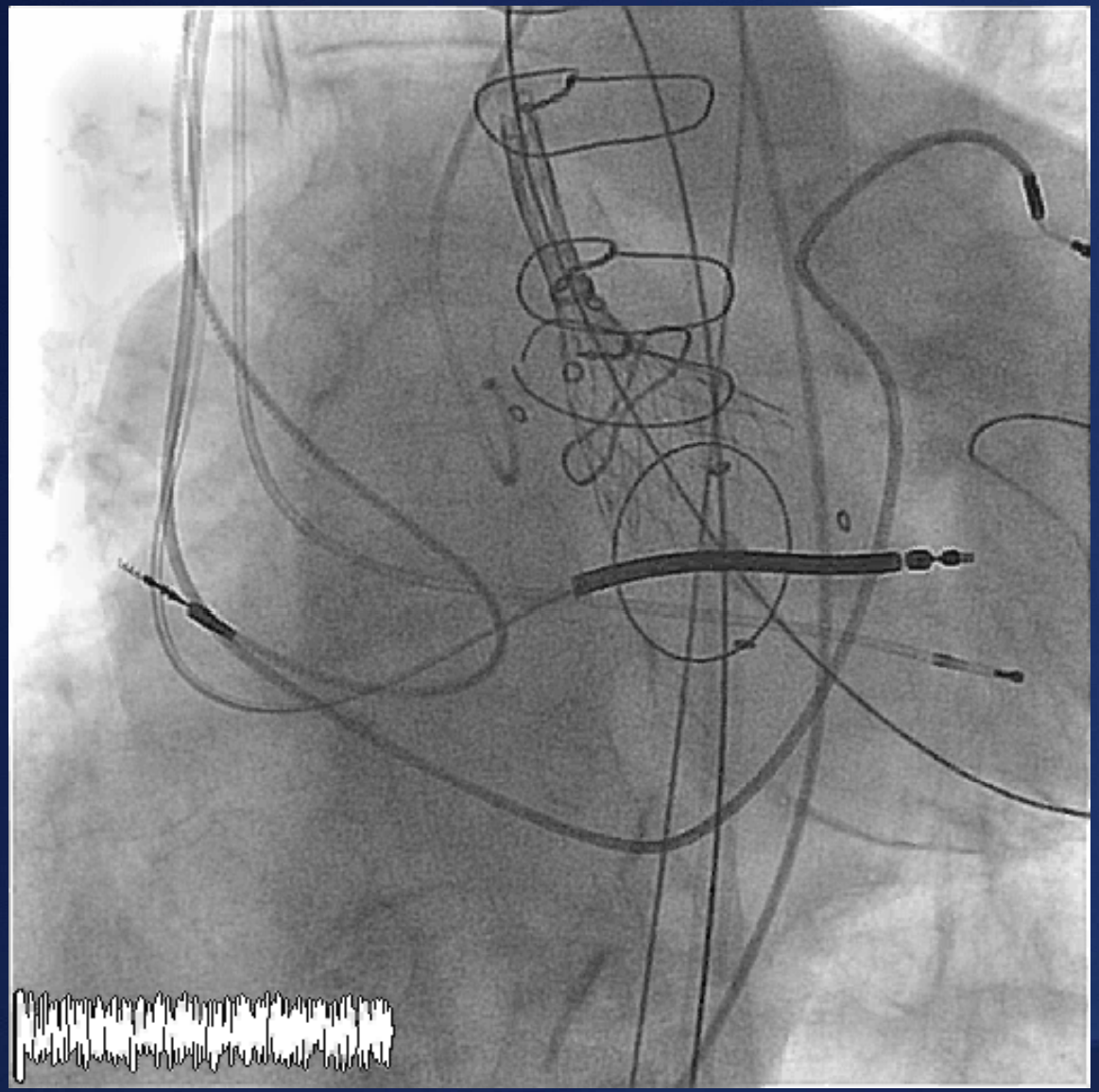
Wear and tear (A) and calcification (B) are the most common reasons for bioprosthetic valve failure

1. Piazza, N, et al. *JACC Cardio Interventions*. 2011;4:721-32.

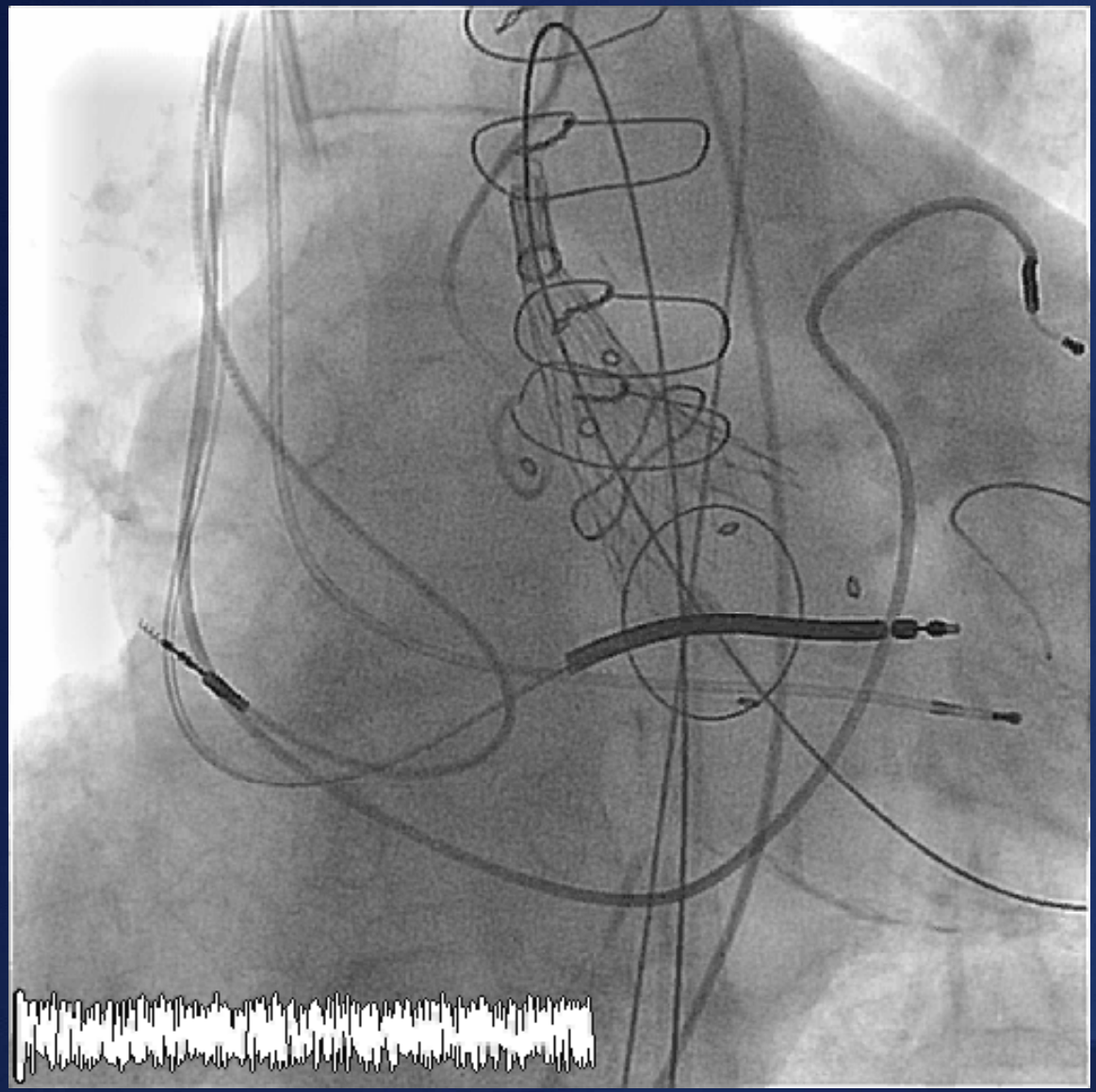
CoreValve in Failed Hancock 23mm



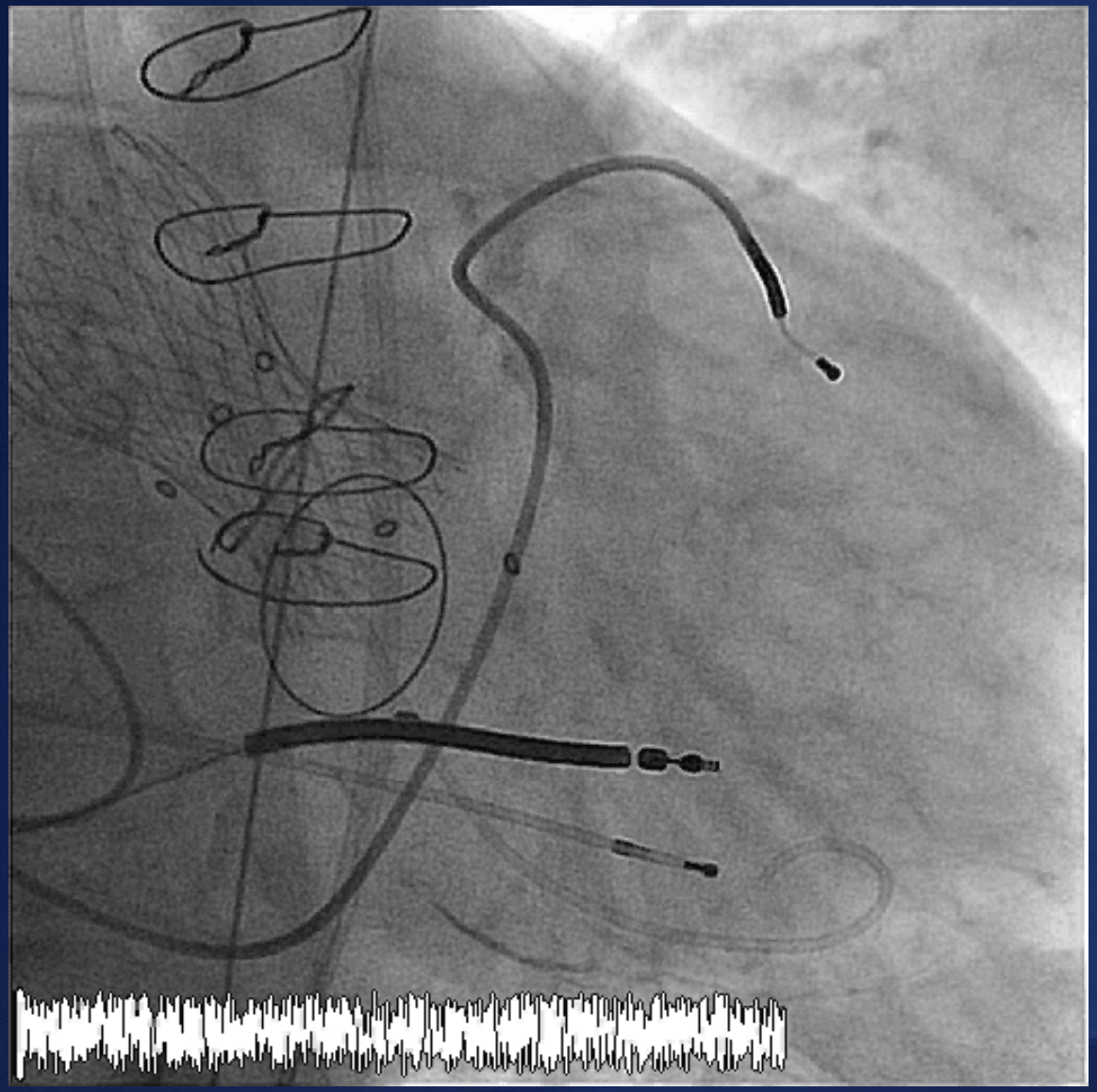
CoreValve in Failed Hancock 23mm



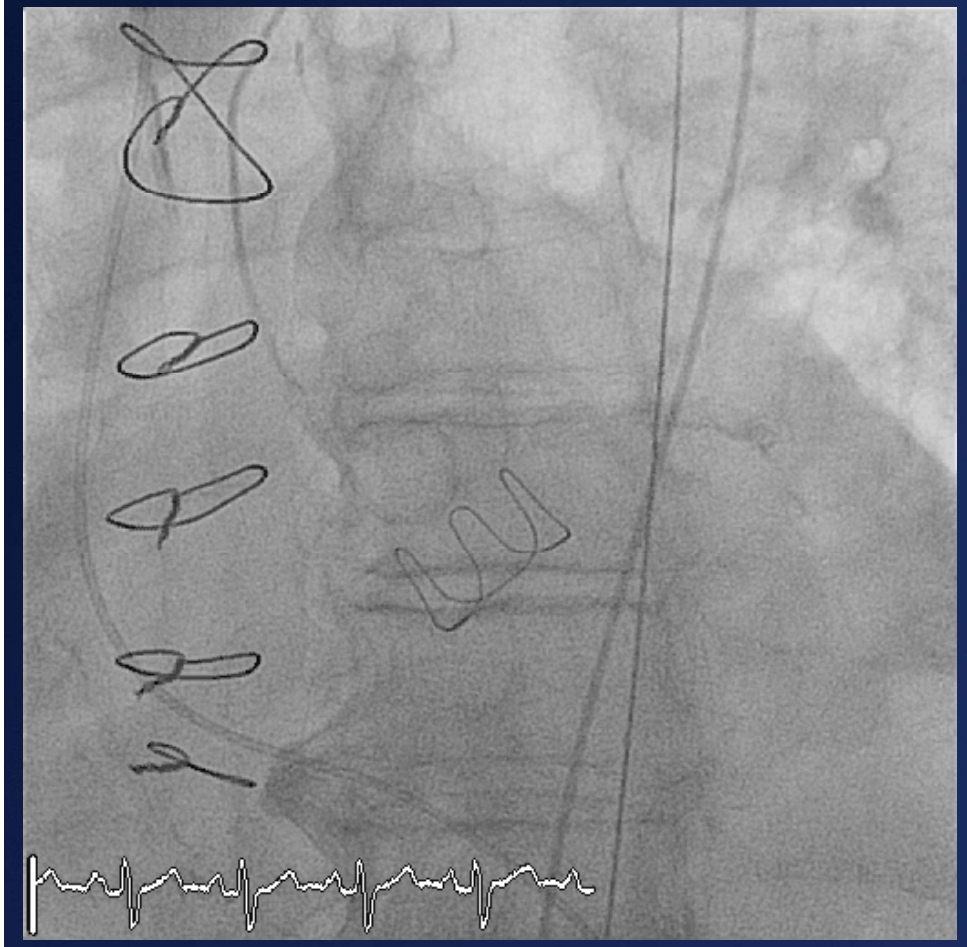
CoreValve in Failed Hancock 23mm

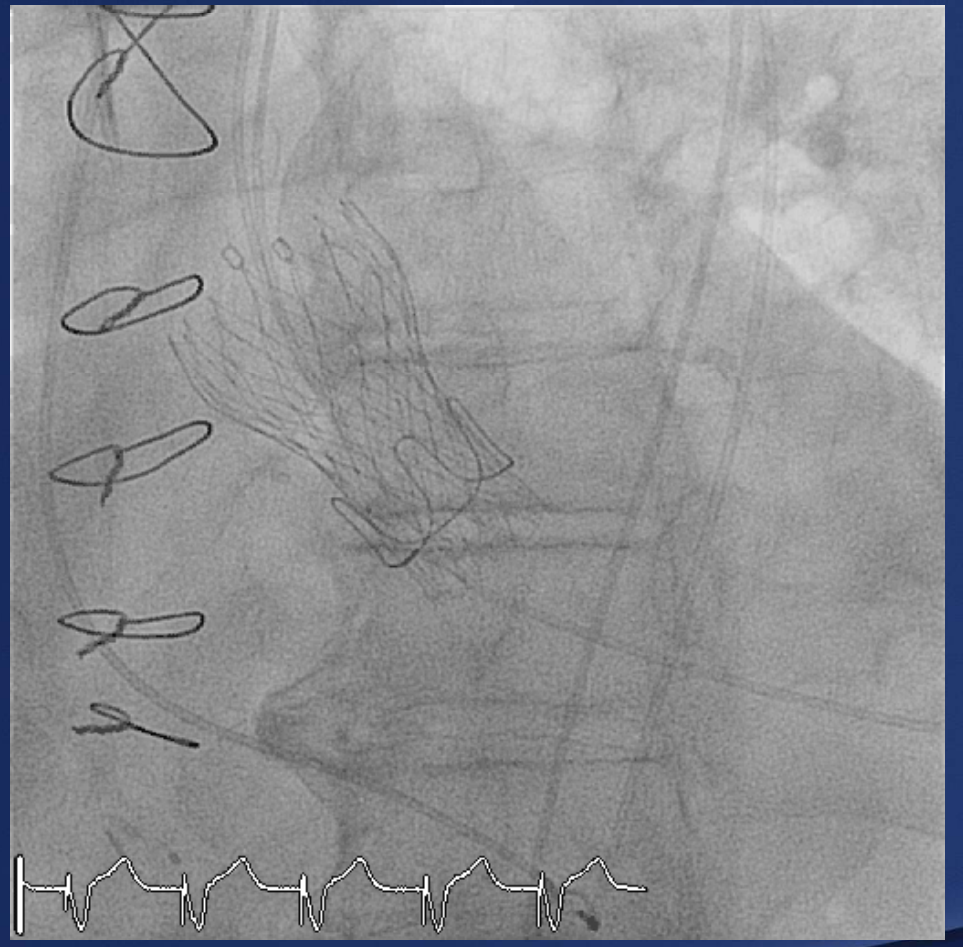


CoreValve in Failed Hancock 23mm



CoreValve in Failed Carpentier 22mm in a Patient with Severely Impaired LVEF





Sapien in Failed Bioprosthesis

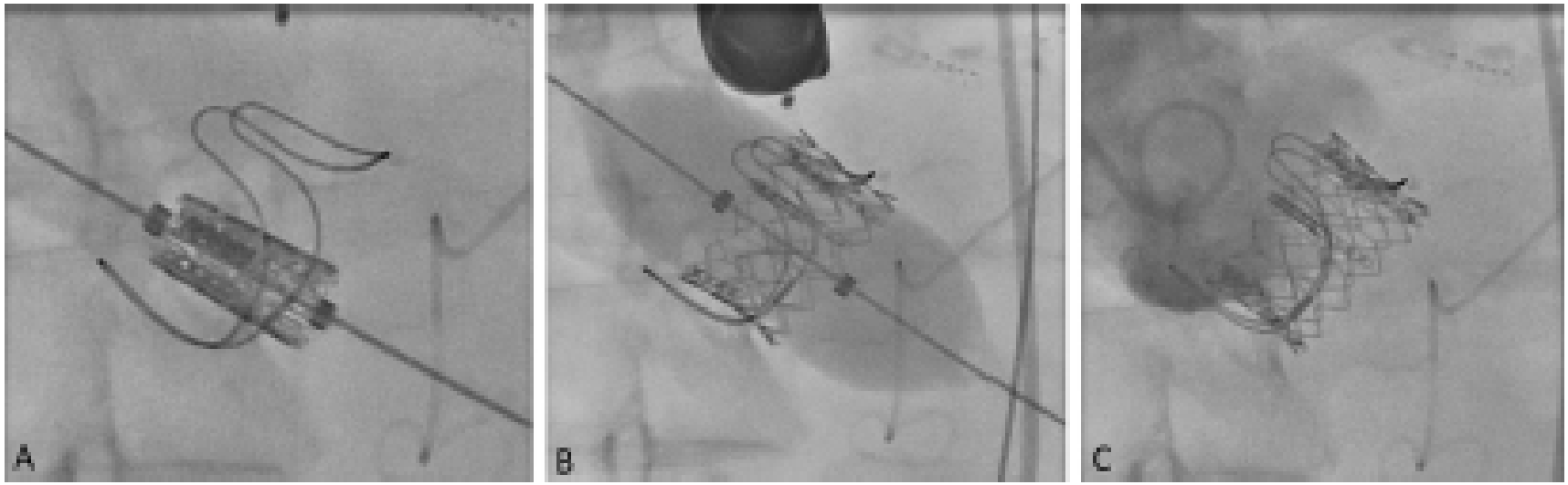
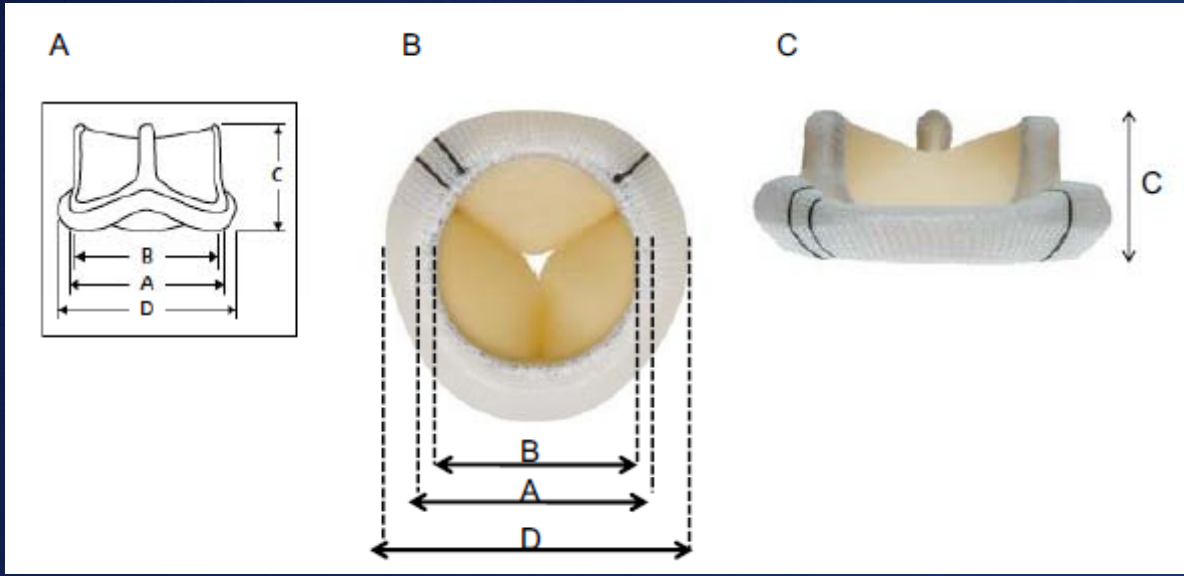


Figure 2. A, Fluoroscopic images during positioning of a transcatheter valve (SAPIEN 23-mm THV). The wire frame of a degenerated surgical bioprosthesis (Carpentier-Edwards 23 mm) is visible. The prosthetic sewing ring below the valve struts is radiolucent. B, The balloon-expandable THV is deployed and fixed within the sewing ring. C, Aortography demonstrates a competent valve (patient 9).

1. Webb J, et al. *Circulation*. 2010

Dimensions of Stented Bioprosthetic Valves [1]



(A) Diagrammatic representation of stented bioprosthetic valve dimensions where

- A outer stent diameter
- B inner stent diameter
- C prosthesis height
- D outer sewing ring diameter.

(B) Inferior (ventricular) view of stented bioprosthesis.
(C) Side view of stented bioprosthesis.

1. Piazza, N, et al. *JACC Cardio Interventions*. 2011;4:721-32.

Bioprosthetic Valves Sizing Chart (per manufacturer) [1]

Valve Label Size	Valve Type/Model (Manufacturer)	Sewing Ring External Diameter, mm	Stent Outer Diameter, mm	Stent Internal Diameter, mm
18	Soprano (Sorin Biomedica)	26	21	17.8
19	Magna (Edwards Lifesciences)	24	19	18
	Perimount (Edwards Lifesciences)	26	19	18
	Mosaic (Medtronic)	25	19	17.5
	Hancock Ultra (Medtronic)	24	19	17.5
	Hancock II (Medtronic)	N/A	N/A	N/A
	Mitroflow (Sorin Biomedica)	21	18.6	15.4
	Trifecta (St. Jude Medical)	24	19	N/a
	Epic/Biocor (St. Jude Medical)	N/A	N/A	N/A
	Epic Supra/Biocor Supra (St. Jude Medical)	N/A	N/A	N/A
20	Soprano (Sorin Biomedica)	28	23	19.8
21	Magna (Edwards Lifesciences)	26	21	20
	Perimount (Edwards Lifesciences)	29	21	20
	Mosaic/Hancock II (Medtronic)	27	21	18.5
	Hancock/Hancock Ultra (Medtronic)	26	21	18.5
	Mitroflow (Sorin Biomedica)	23	20.7	17.3
	Trifecta (St. Jude Medical)	26	21	N/A
	Epic/Biocor (St. Jude Medical)	N/A	21	19
	Epic Supra/Biocor Supra (St. Jude Medical)	N/A	21	21
22	Soprano (Sorin Biomedica)	30	25	21.7
23	Magna (Edwards Lifesciences)	28	23	22
	Perimount (Edwards Lifesciences)	31	23	22
	Mosaic/Hancock II (Medtronic)	30	23	20.5
	Hancock/Hancock Ultra (Medtronic)	28	23	22
	Mitroflow (Sorin Biomedica)	26	22.7	19
	Trifecta (St. Jude Medical)	28	23	N/A
	Epic/Biocor (St. Jude Medical)	N/A	23	21
	Epic Supra/Biocor Supra (St. Jude Medical)	N/A	23	23

1. Gurvitch, R, et al. *JACC*. 2011;58:2196-209.

TAVI in Failed TAVI

First Valve-in-Valve Direct Transaortic CoreValve Implantation in an Insufficient Sapien Valve

Bas T. G. van der Lienden, MD,* Ben M. Swinkels, MD,* Robin H. Heijmen, MD, PhD,†
E. Gijs Mast, MD,* Thom L. De Kroon, MD,† Jurriën M. ten Berg, MD, PhD*

Nieuwegein, the Netherlands

10 months post implantation, patient experienced symptoms with moderate-to-severe central insufficiency; redo successfully performed with CoreValve by direct aortic access

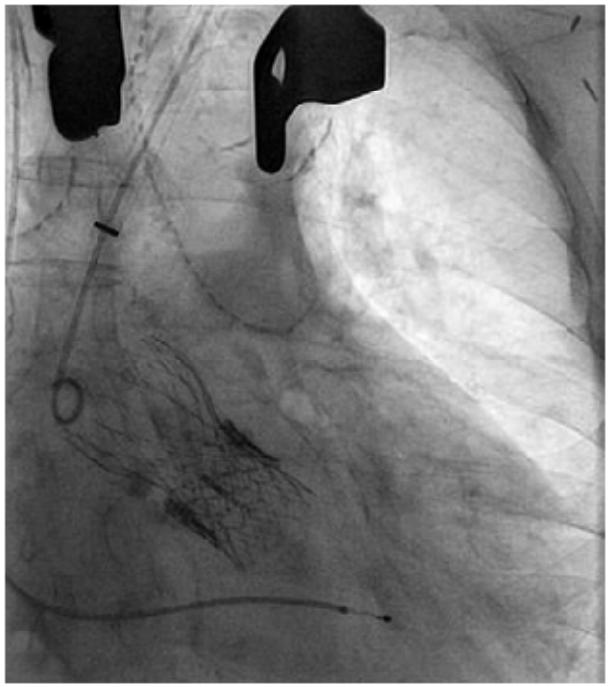


Figure 1. CoreValve in Sapien Valve

Coronary angiography at the end of the procedure showing the 26-mm CoreValve prosthesis (Edwards Lifesciences, Inc., Irvine, California) deployed at the intended position inside the Sapien valve, with direct aortic access.

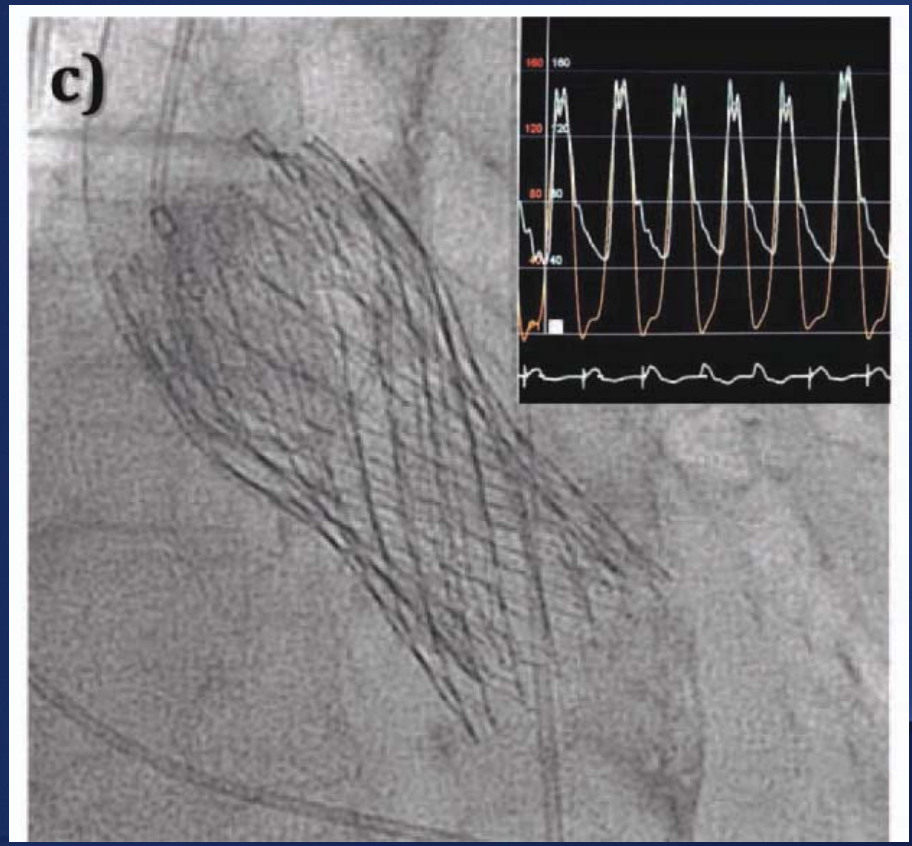
1. Van der Lienden, et al. *JACC Cardiovascular Interventions*. 2011.

TAVI in Failed TAVI

Treatment of a Degenerative Stenosed Corevalve® Aortic Bioprosthesis by Transcatheter Valve-In-Valve Insertion

Christoph Hammerstingl,* MD, Georg Nickenig, MD, PhD, and Eberhard Grube, MD, PhD

5.5 years post CoreValve implantation, patient presented with HF symptoms; echo revealed critical AV-stenosis due to heavily calcified bioprosthetic valve leaflets. CoreValve ViV successfully implanted.



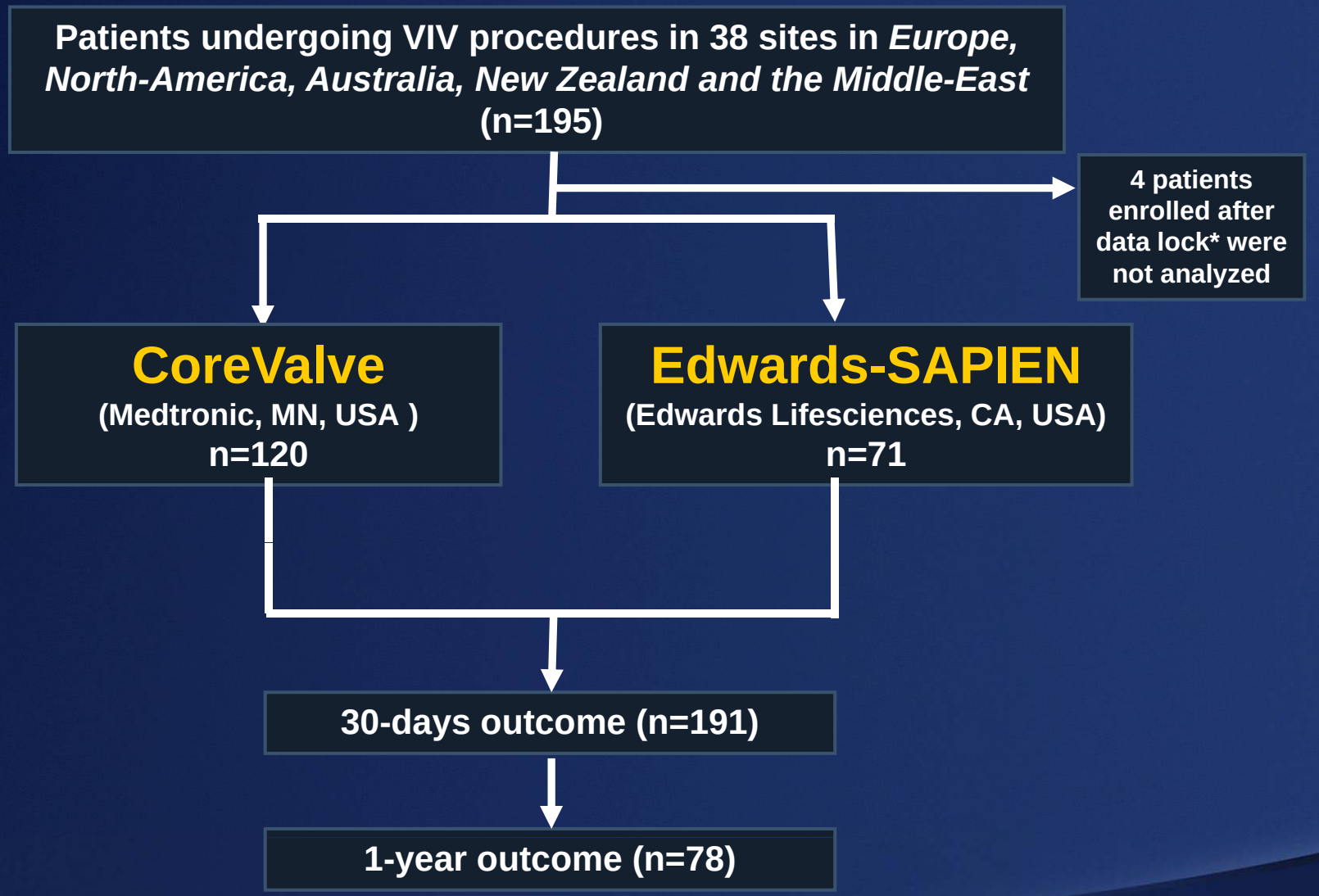
1. Hammerstingl, et al. *Catheterization & Cardiovascular Interventions*. 2011.

Transcatheter Aortic-Valve Implantation for the Treatment of Degenerative Bioprosthetic Surgical Valves: Results from the Global Valve-in-Valve Registry

Danny Dvir, John Webb, Stephen Brecker, Sabine Bleiziffer, David Hildick-Smith, Antonio Colombo, Fleur Descoutures, Neil E Moat, Luca Testa, Christian Hengstenberg, Raffi Bekerdjian, Thierry Lefevre, Victor Guetta, Henrik Nissen, José-María Hernández, David Roy, Federico De Marco, Rui Teles, Amit Segev, Andreas Baumbach, Nicolas Dumonteil, Claudia Fiorina, Dan Ioanes, Michael Gotzmann, Massimo Napodano, Didier Tchetche, Gian P Ussia, Marc W Merx, Mohamed Abdel-Wahab, Jean-Claude Laborde, Ran Kornowski

1. Divir, D. Global Valve Registry. TCT 2011.

Global Valve in Valve Registry[1]



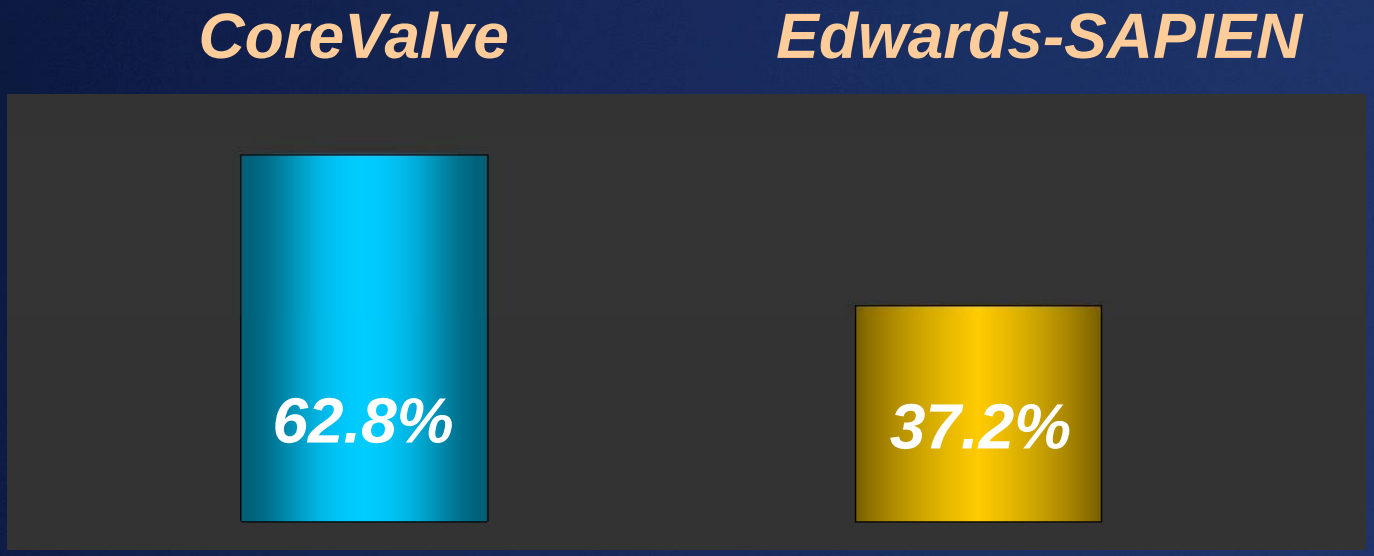
1. Divir, D. Global Valve Registry. TCT 2011.

Baseline Demographics at Time of VIV

	CoreValve group *n=120*	*Edwards-SAPIEN* group *n=71*	*P*
Age (yrs)	77.2 ± 11.1	78.4 ± 9.7	0.44
Gender (% male)	51.7	52.1	1.0
LogEuroSCORE	30.8 ± 19.7	31.4 ± 17.2	0.83
STS score	14.0 ± 13.9	10.3 ± 9.4	0.01
Diabetes Mellitus (%)	34.5	21.1	0.05
Peripheral Vascular Disease (%)	17.7	22.5	0.41
Chronic Renal Failure (%)	43.3	52.1	0.24
Previous stroke (%)	13.3	9.9	0.48

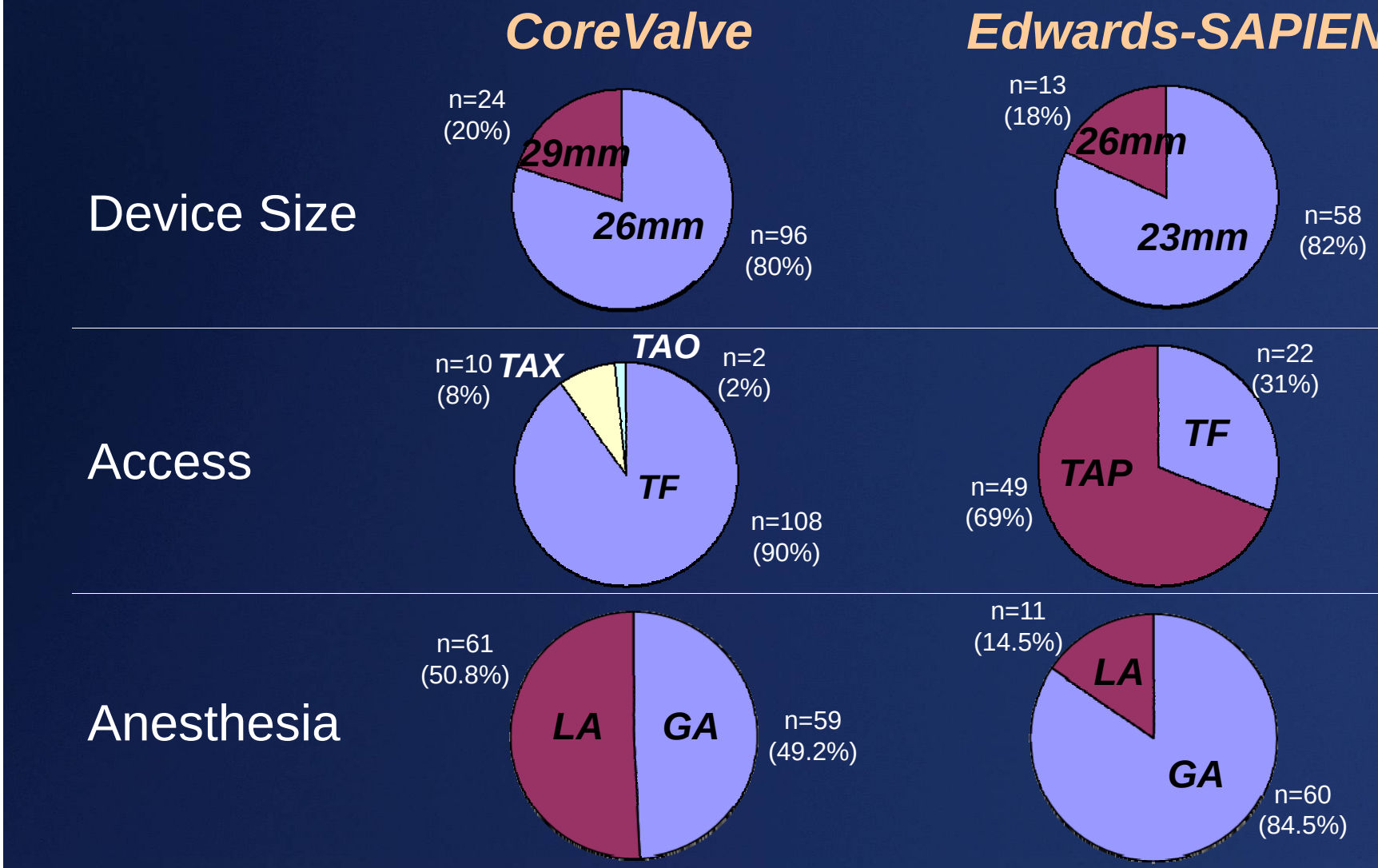
1. Divir, D. Global Valve Registry. TCT 2011.

Valve in Valve Procedures



1. Divir, D. Global Valve Registry. TCT 2011.

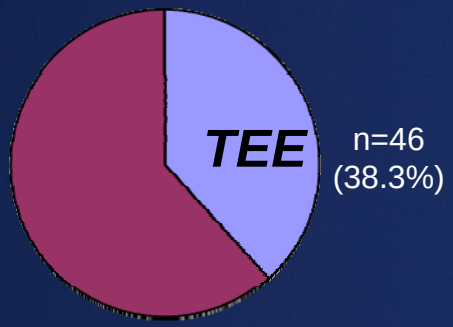
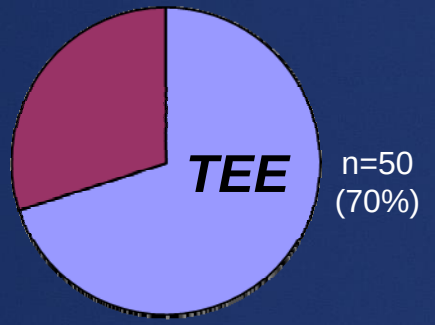
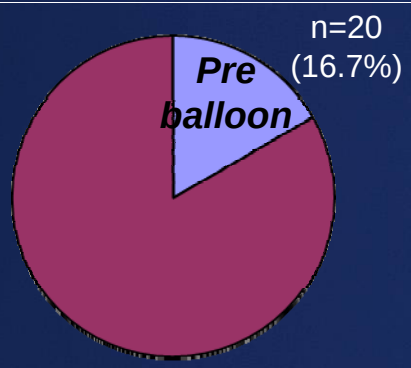
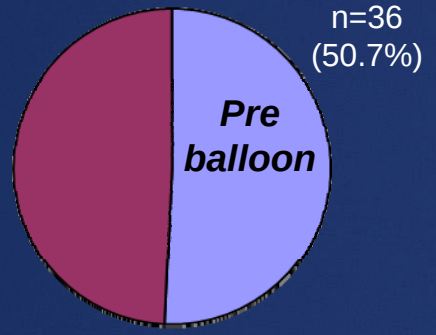
Valve in Valve Procedures



TF= Transfemoral; TAP= Transpical; TAX= Transaxillary; TAO= transaaortic; GA= General Anesthesia; LA= Local Anesthesia

1. Divir, D. Global Valve Registry. TCT 2011.

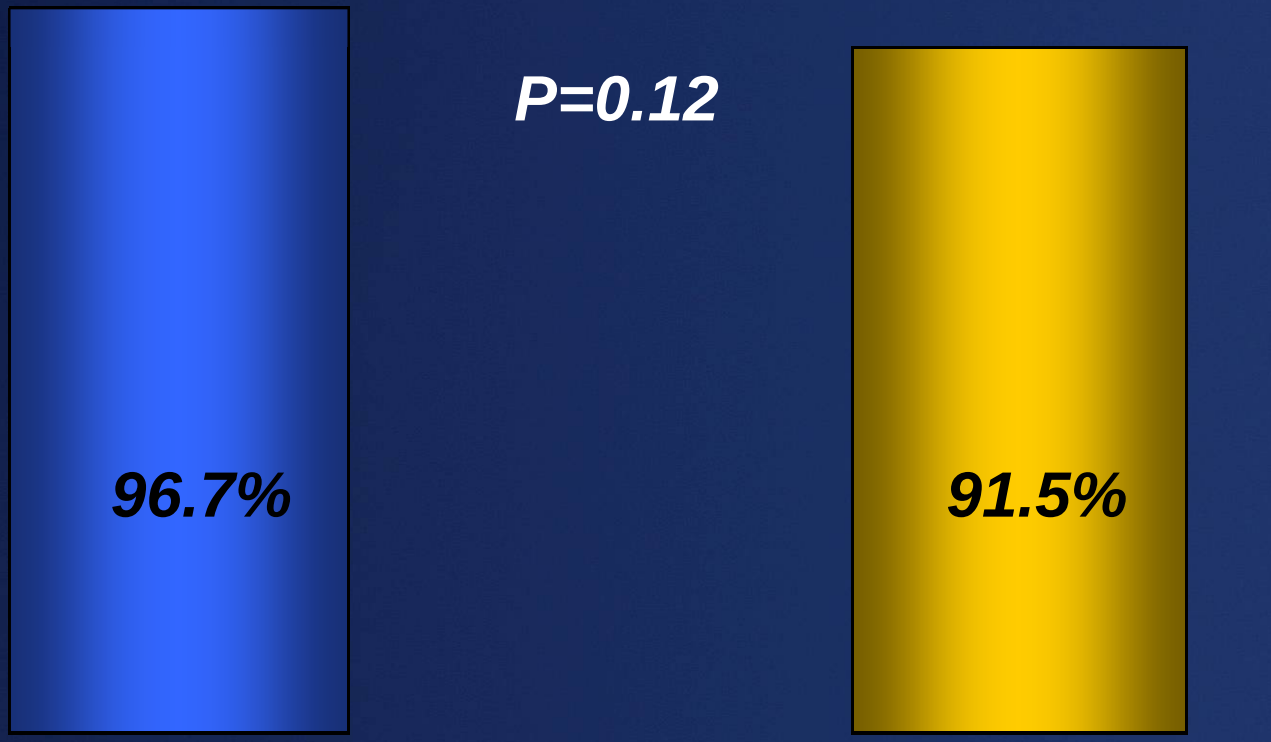
Valve in Valve Procedures

	CoreValve	*Edwards-SAPIEN*
TEE usage		
Pre- Balloon Inflation		

1. Divir, D. Global Valve Registry. TCT 2011.

Valve in Valve Procedures

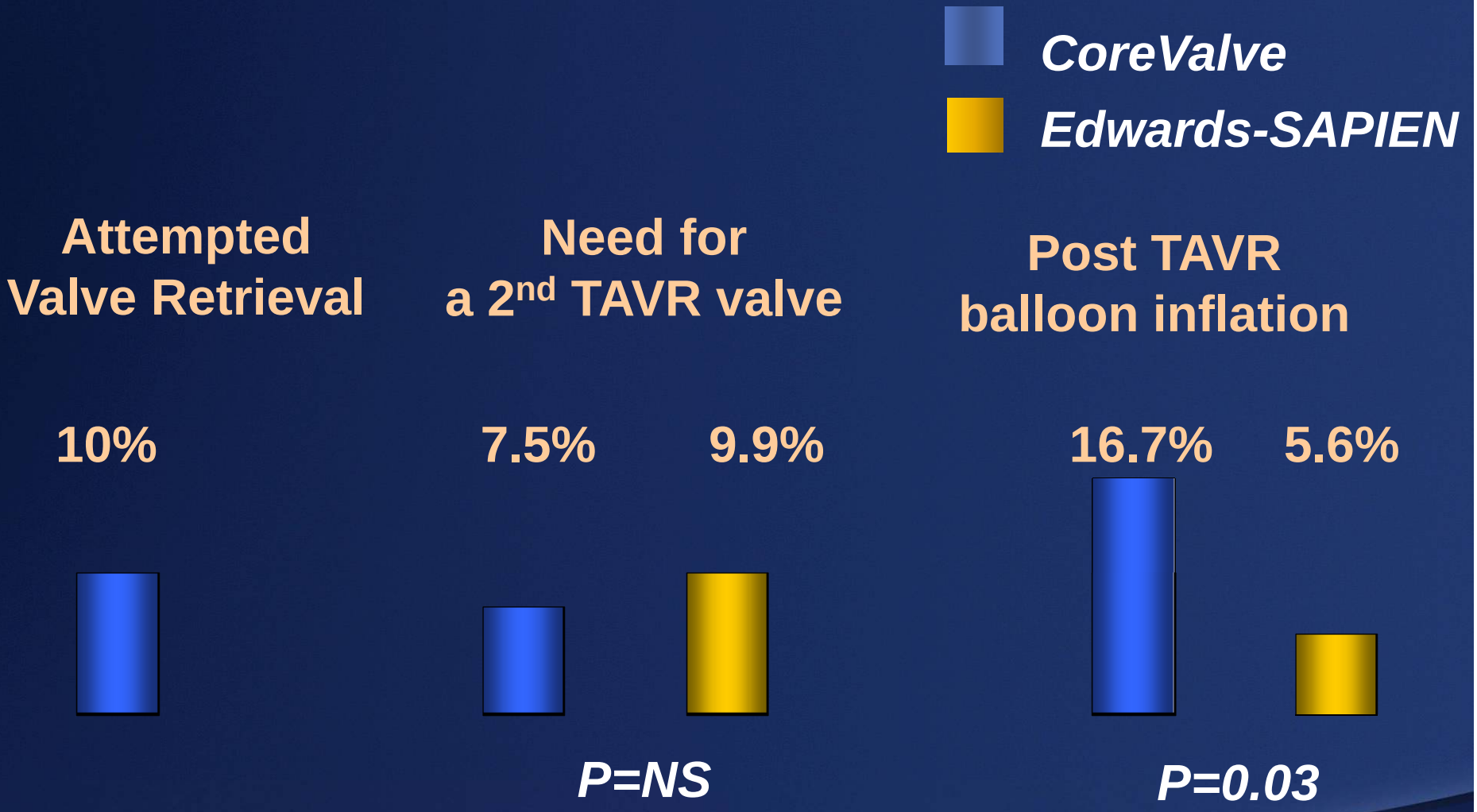
Implantation success



1. Divir, D. Global Valve Registry. TCT 2011.

Valve in Valve Procedures

Intraprocedural Results



1. Divir, D. Global Valve Registry. TCT 2011.

Valve in Valve Procedures

Intraprocedural Results

Ostial Coronary Obstruction

3.3% **4.2%**

P=NS

Need for An Emergent Surgery

0.8% **4.2%**

P=0.11

1. Divir, D. Global Valve Registry. TCT 2011.

Valve in Valve Procedures

30-day outcome

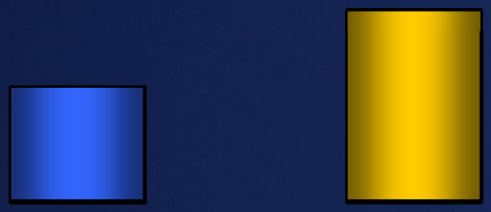
CoreValve

Edwards-SAPIEN

Median Duration of hospital stay- **8 days**

All cause mortality

7.5% **12.7%**



P=0.24

CV mortality

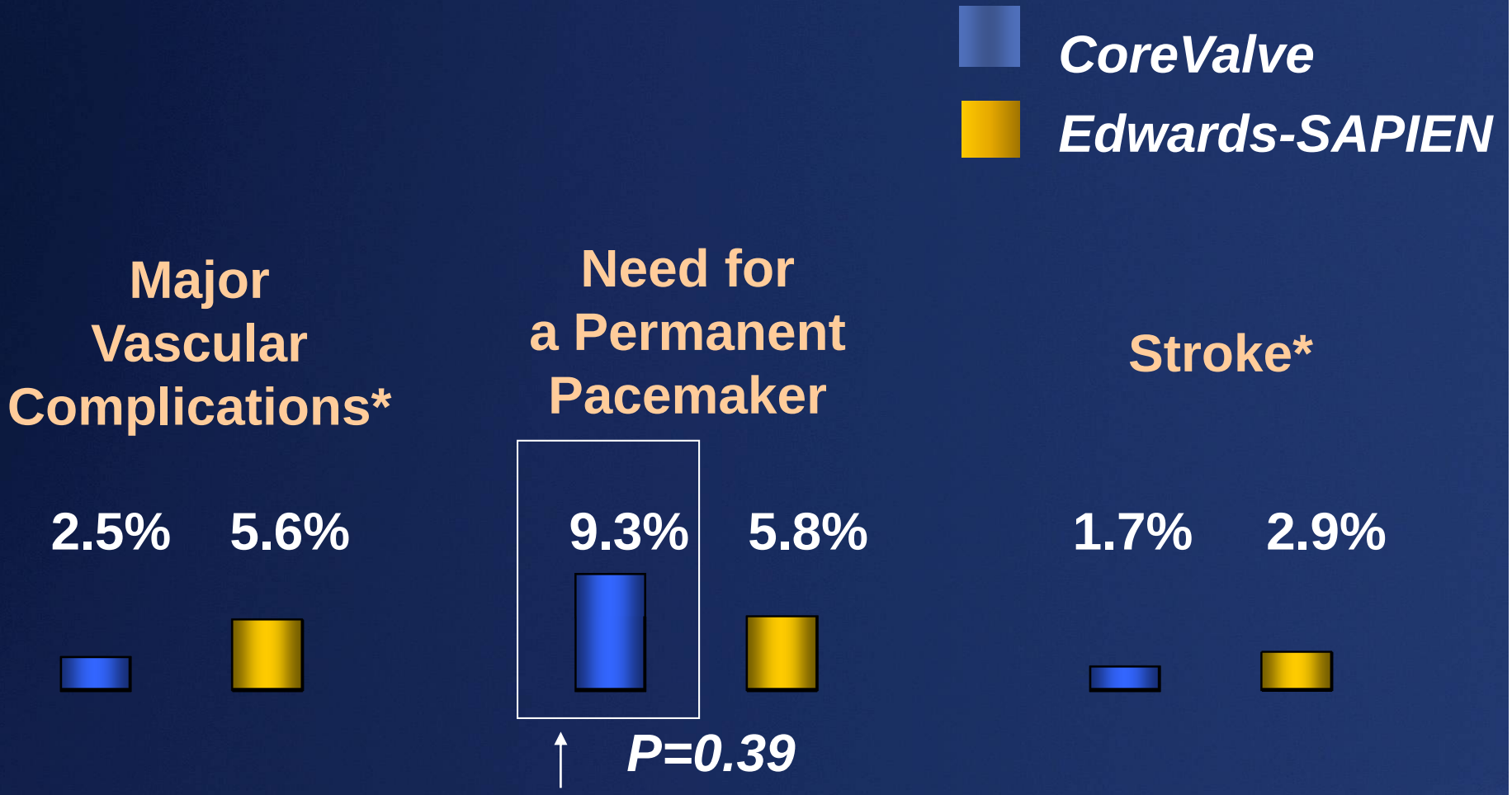
5.8% **11.3%**

P=0.18

1. Divir, D. Global Valve Registry. TCT 2011.

Valve in Valve Procedures

30-day outcome



Lower than in most CoreValve registries

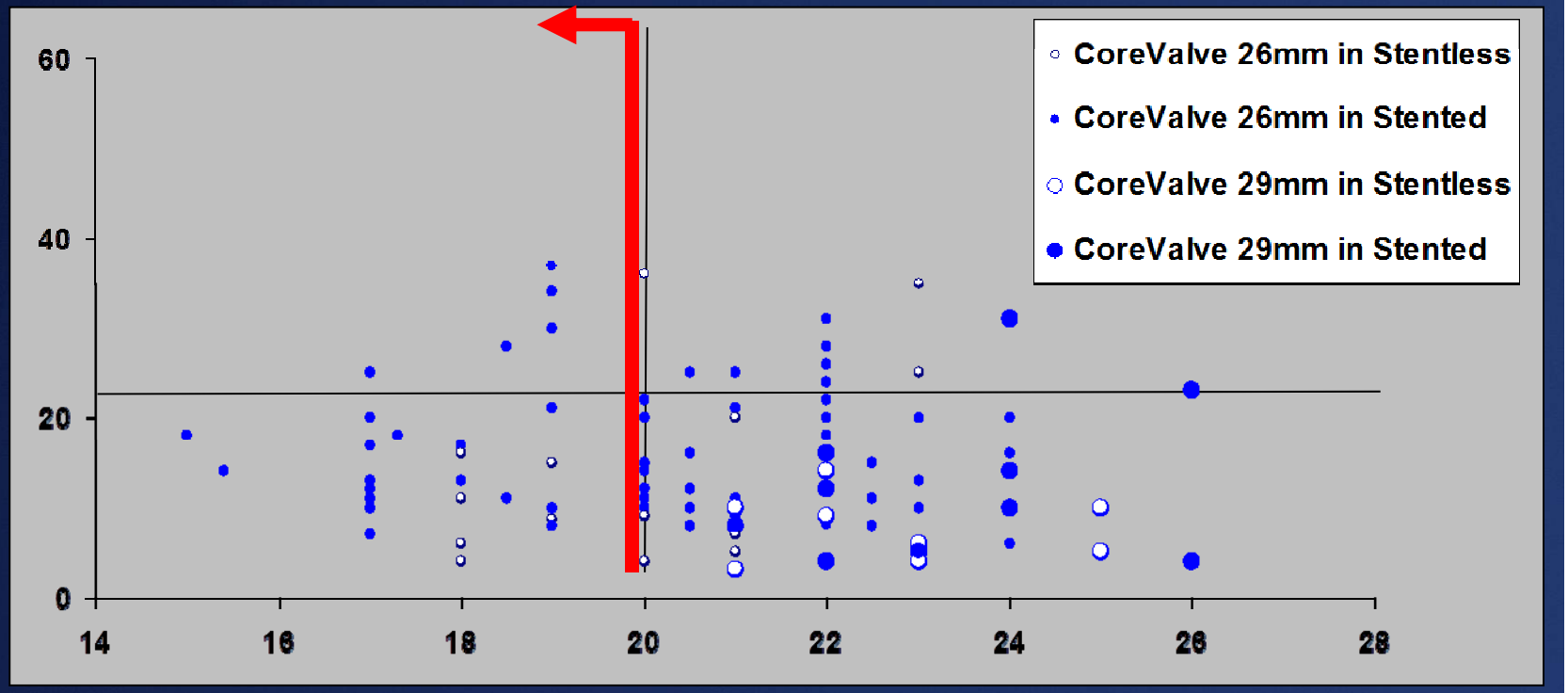
** VARC definition*

1. Divir, D. Global Valve Registry. TCT 2011.

Post Procedural Gradients

CoreValve Device

Mean Aortic-Valve Gradients (mmHg)



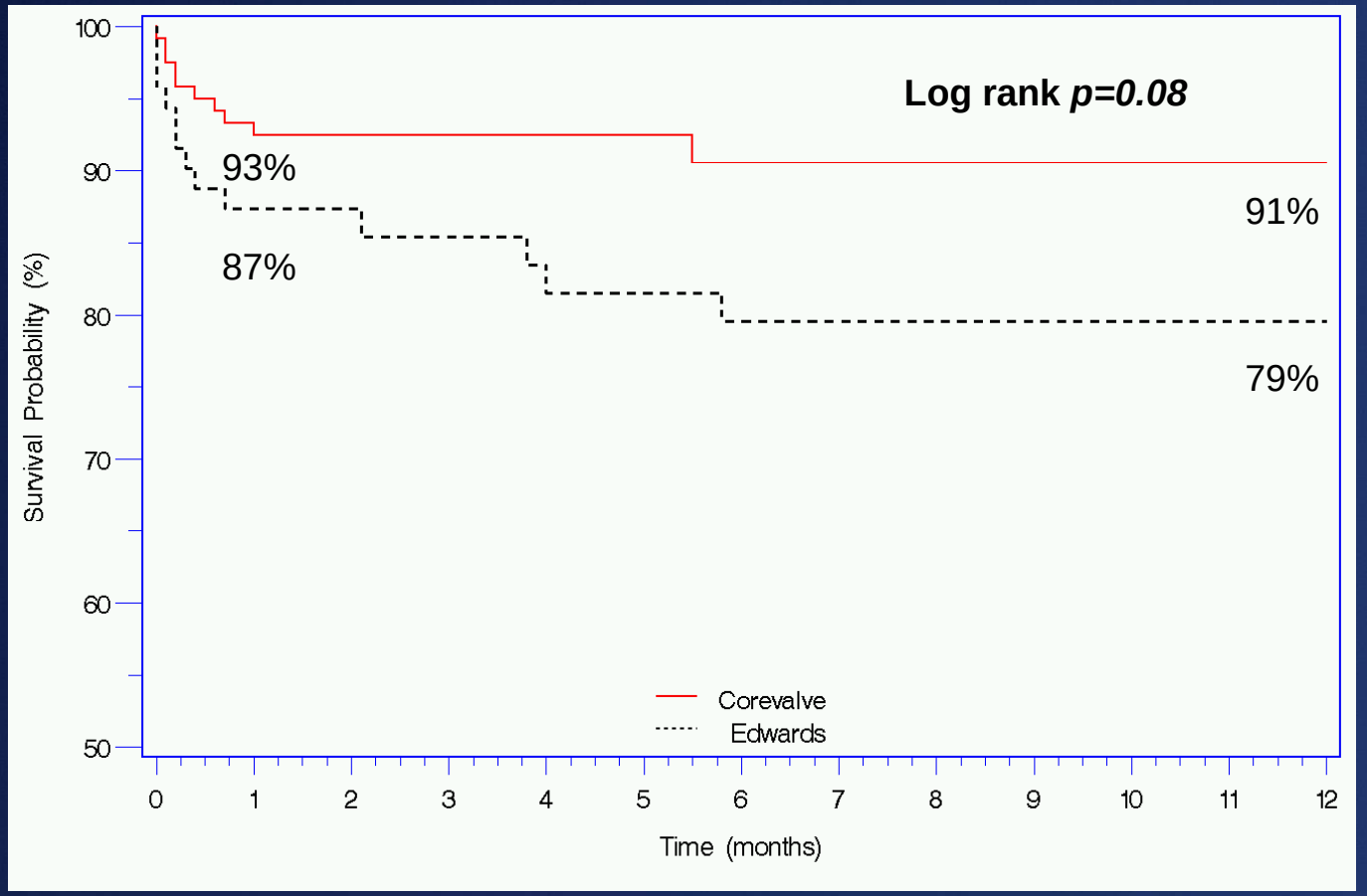
Surgical Bioprosthesis *Internal* Diameter (mm)

In small surgical bioprosthesis (<20mm ID)- 25.9% had elevated gradients

1. Divir, D. Global Valve Registry. TCT 2011.

*** Mean aortic-valve gradient> 20mmHg.**

1-year Kaplan Meier Survival Curves of patients who underwent VIV procedures



1. Divir, D. Global Valve Registry. TCT 2011.

Conclusions

- The VIV procedure, although feasible, is technically demanding and should be reserved for highly experienced centers.
- The technique is clinically effective in most patients, with 1-year results comparable with other TAVR cohorts.
- Significantly elevated post procedural gradients are common after VIV procedures, especially in relatively small bioprosthetic devices treated with currently available Edwards-SAPIEN valves.
- Possible impact of elevated gradients on valve durability should be examined in long-term.

1. Divir, D. Global Valve Registry. TCT 2011.