TAVR Future Directions: New Technology and New Clinical Indications

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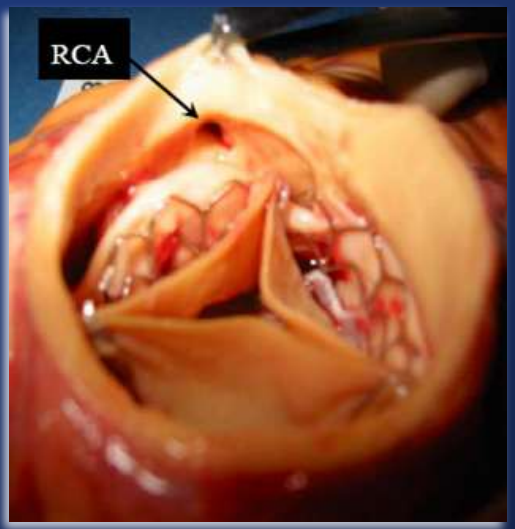
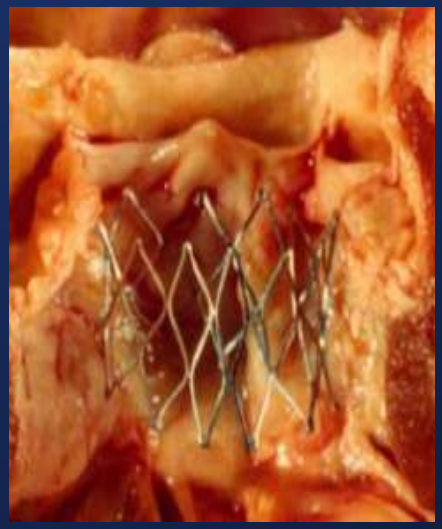
Financial disclosure: None

Transcatheter Aortic Valve Replacement

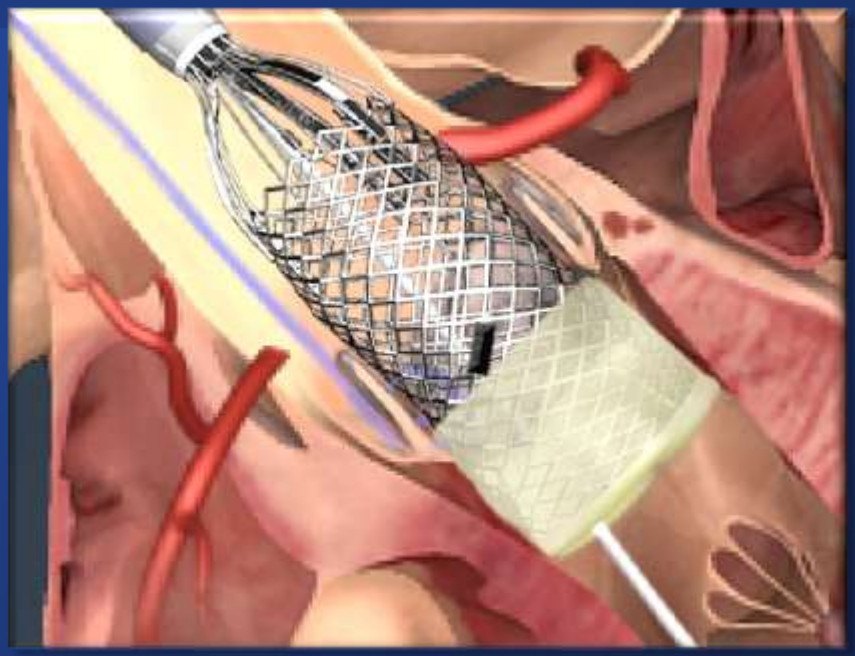
April 16, 2002
Dr. Alain Cribier

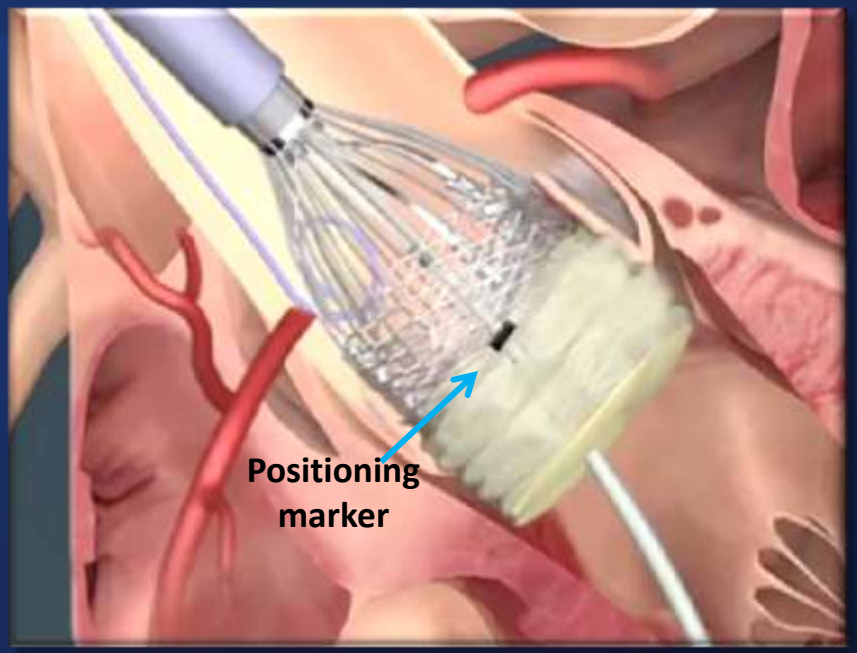




Lotus Valve System Design Goals

Controlled, Accurate, and Predictable Positioning





- Central radiopaque positioning marker to guide placement
- Valve is repositionable throughout entire deployment process
- Ability to assess valve in final position: valve still repositionable & retrievable prior to release

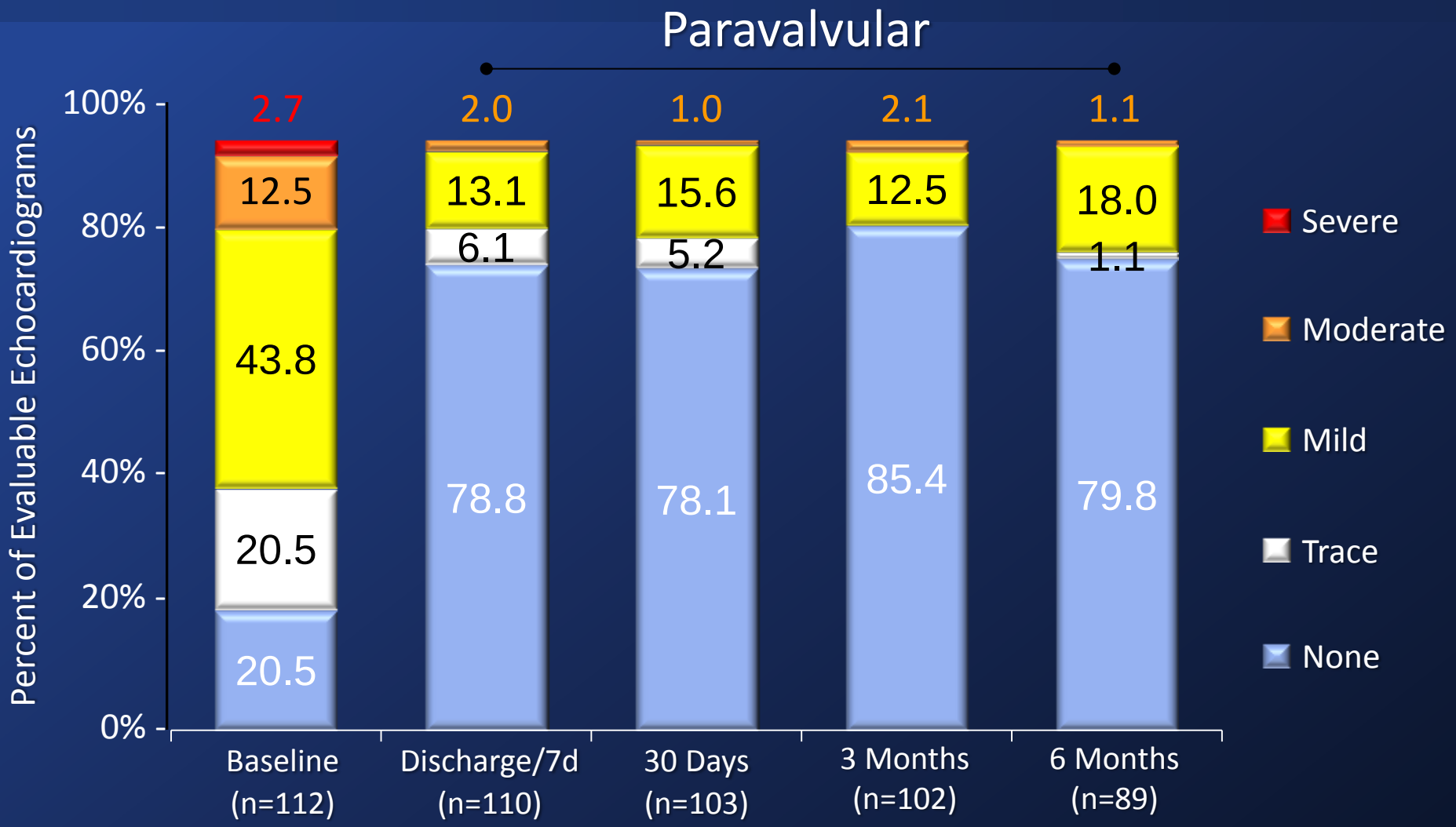
REPRISE II Trial
6-Month Safety Results

	Patients (N=119*)
All-cause mortality (Primary Safety Endpoint at 30 days)	8.4% (10/119)
Disabling stroke†	3.4% (4/119)
Myocardial infarction	3.4% (4/119)
Life-threatening or disabling bleeding	5.0% (6/119)
Major vascular complication	2.5% (3/119)
New permanent pacemaker	29.4% (35/119)
LVOT overstretch ≥10%	57.1% (20/35)
Annulus overstretch ≥10%	40.0% (14/35)

† Neurologic assessment was performed on all patients pre- and post-procedure. * 1 pt withdrew consent; Meredith AM, EuroPCR 2014

REPRISE II Aortic Regurgitation

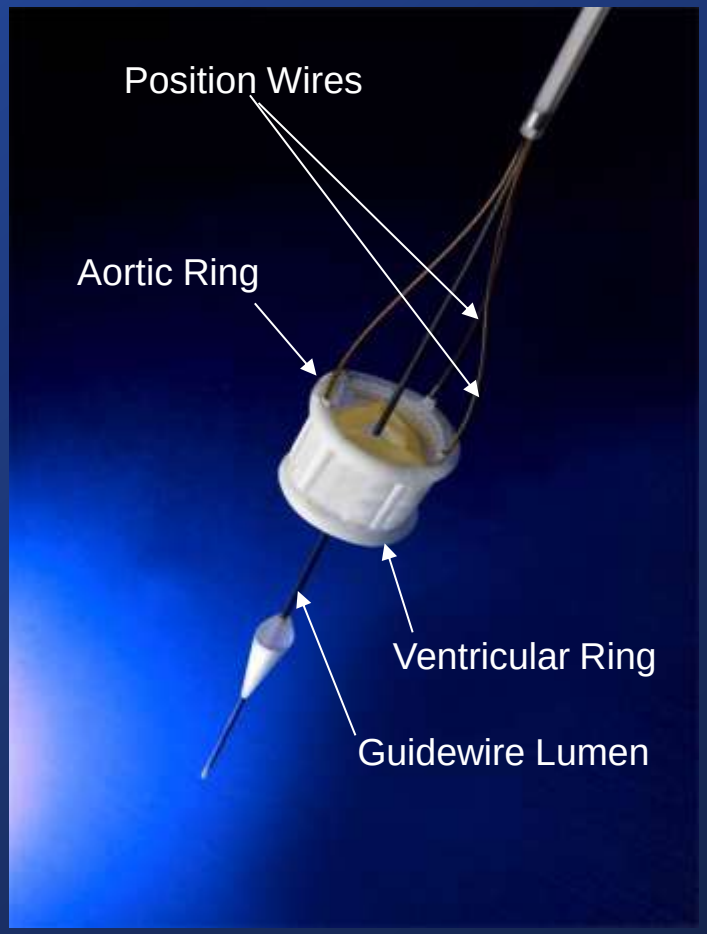
Paravalvular Aortic Regurgitation Over Time

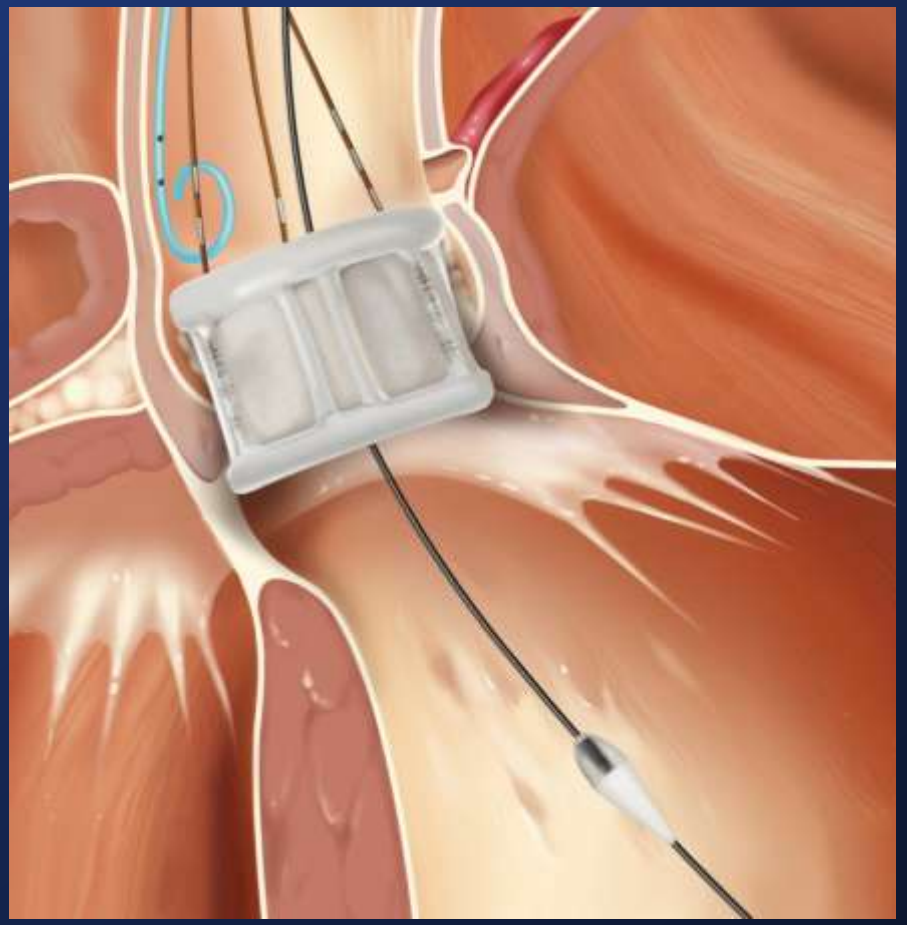


No severe paravalvular aortic regurgitation post-implantation

Ian Meredith AM, MBBS, PhD at EuroPCR 2014

Direct Flow Medical Valve





Direct Flow Medical

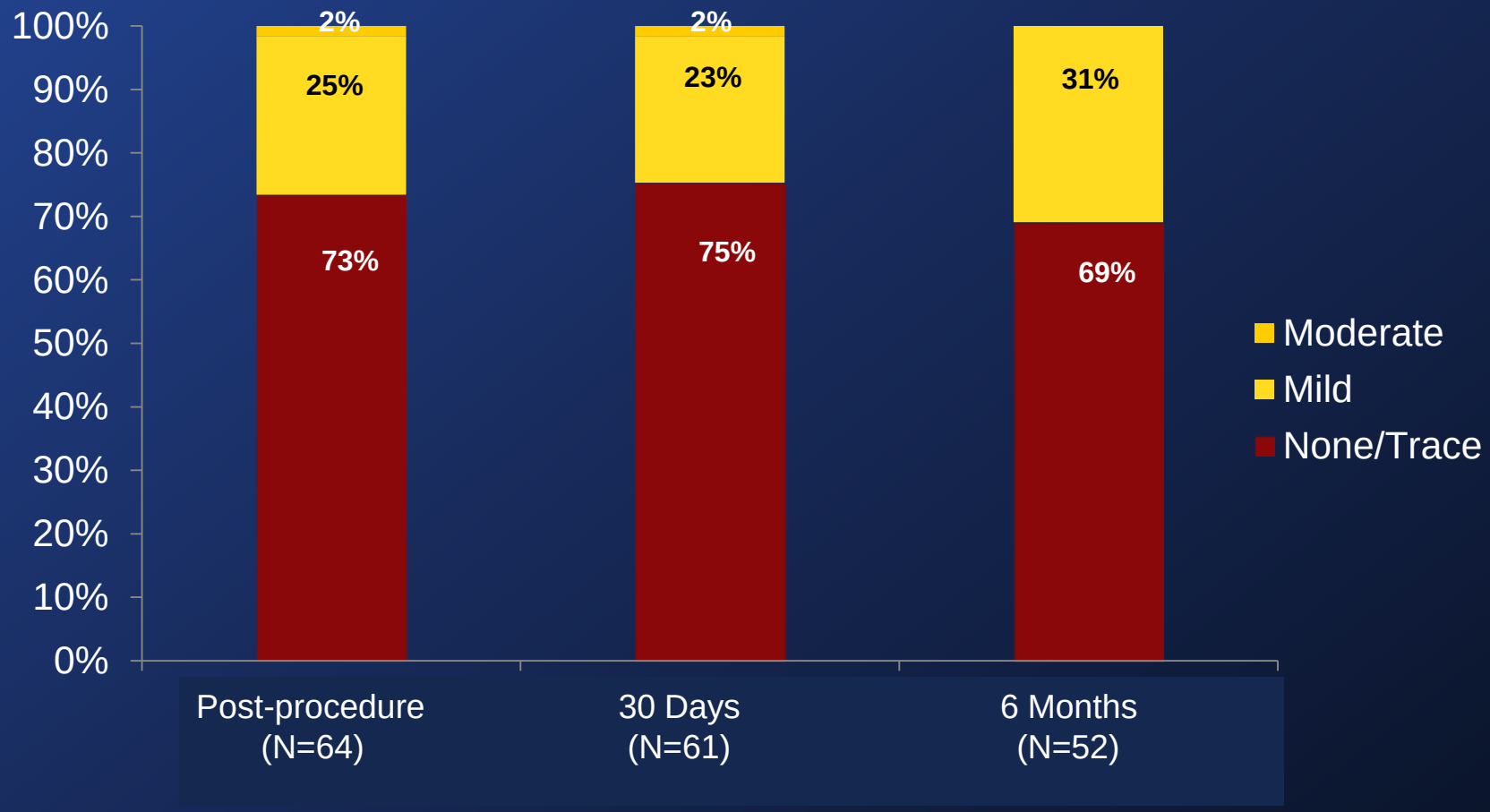
30 Day Results

Study	Discover (n=75)	Registry (n=105)	SALUS (n=30)
Death (%)	1.3	1.9	3
MI (%)	1.3	0	3
Stroke (%)	4.0	1.9	0
Major vascular complication (%)	2.7	3.8	6.7
≥ Moderate AR(%)	1.7	2.0	0
PPM (%)	1.7	6.0	3.3

Direct Flow Medical Valve

Paravalvular Aortic Regurgitation

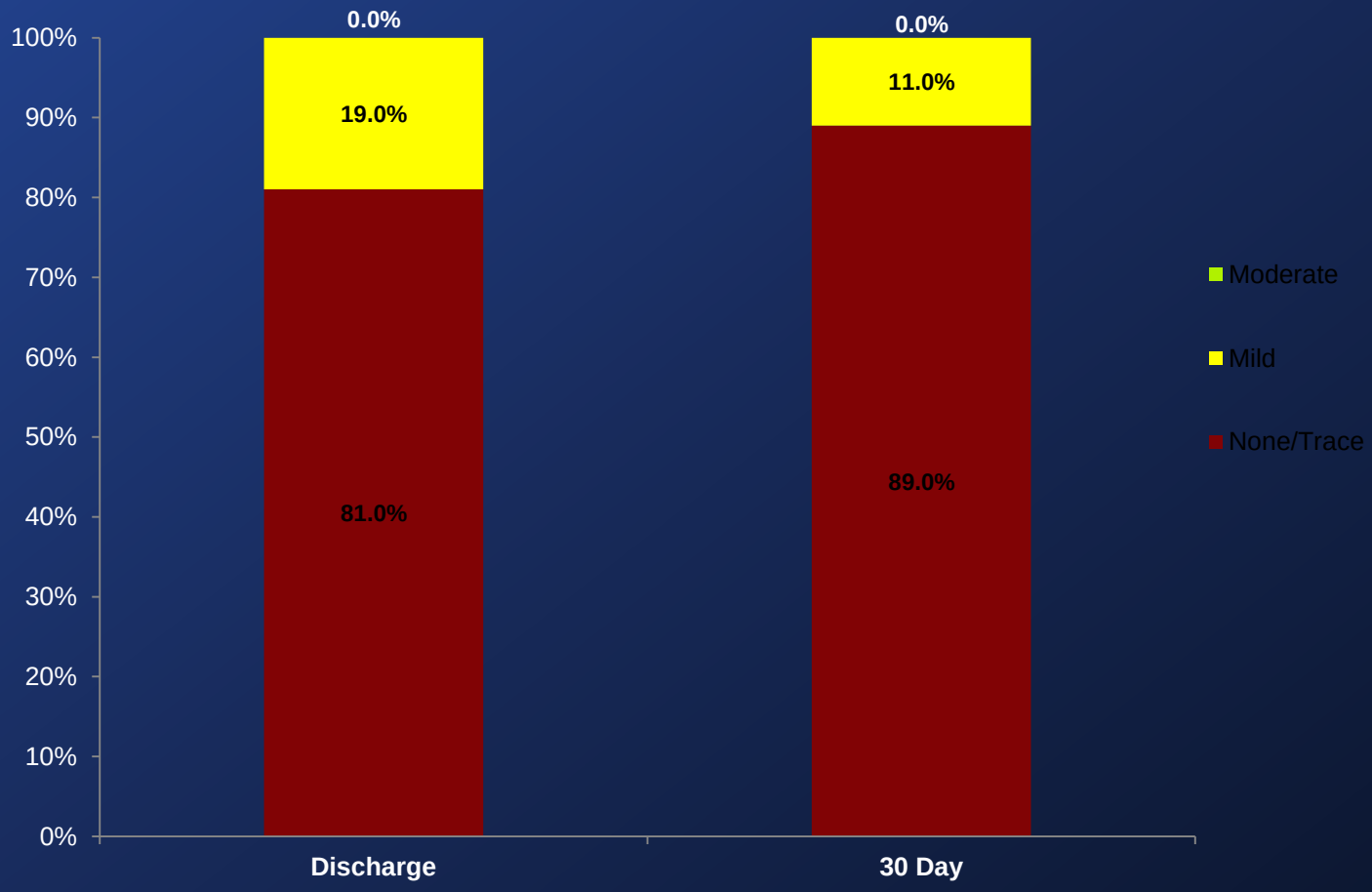
DISCOVER Trial



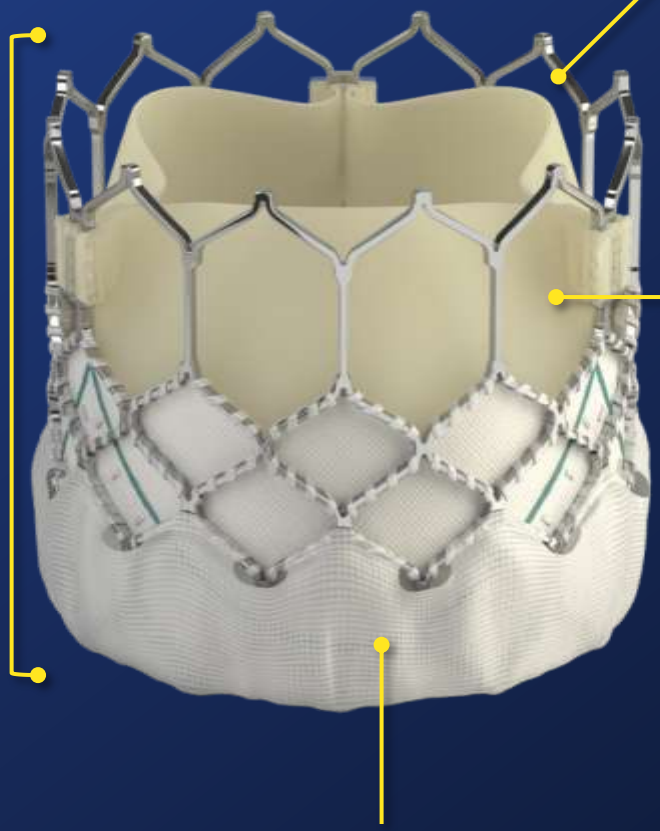
Direct Flow Medical Valve

Paravalvular Aortic Regurgitation

SALUS Feasibility Trial



SAPIEN 3 Transcatheter Heart Valve
Distinguishing Features

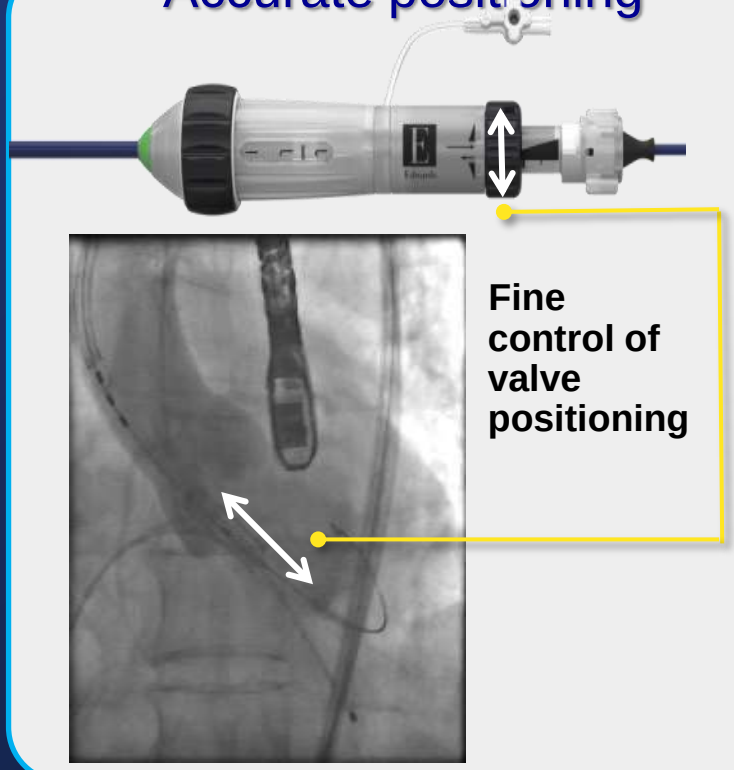


SAPIEN 3 Commander Delivery System

Distinguishing Features

Improved coaxial alignment

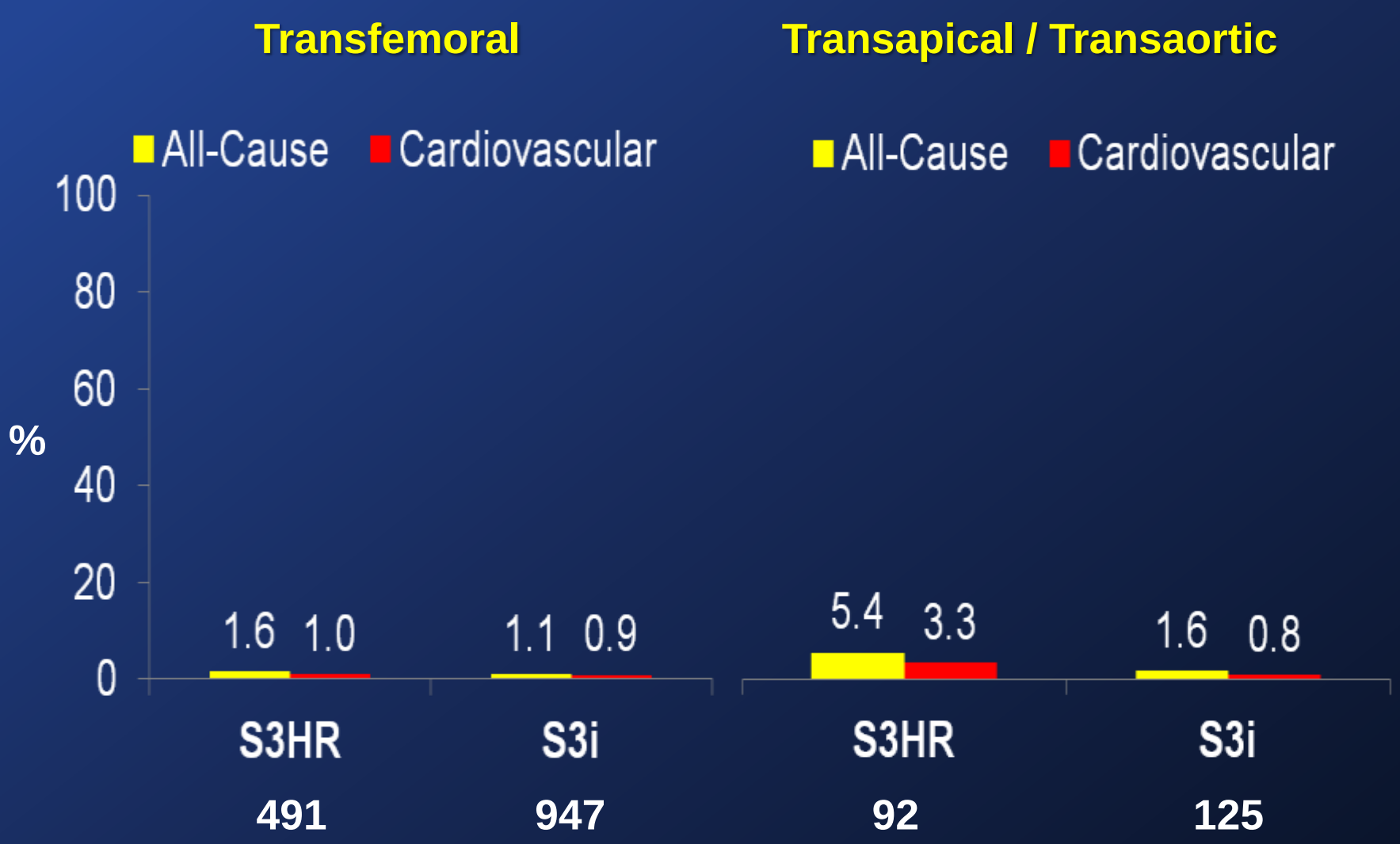
Accurate positioning



SAPIEN 3 Valve Size	20 mm	23 mm	26 mm	29 mm
Expandable Sheath	14F	14F	14F	16F
Minimum Access Vessel Diameter	5.5 mm	5.5 mm	5.5 mm	6.0 mm

Mortality: S3HR & S3i

At 30 Days (As Treated Patients)



Kodali ACC 2015

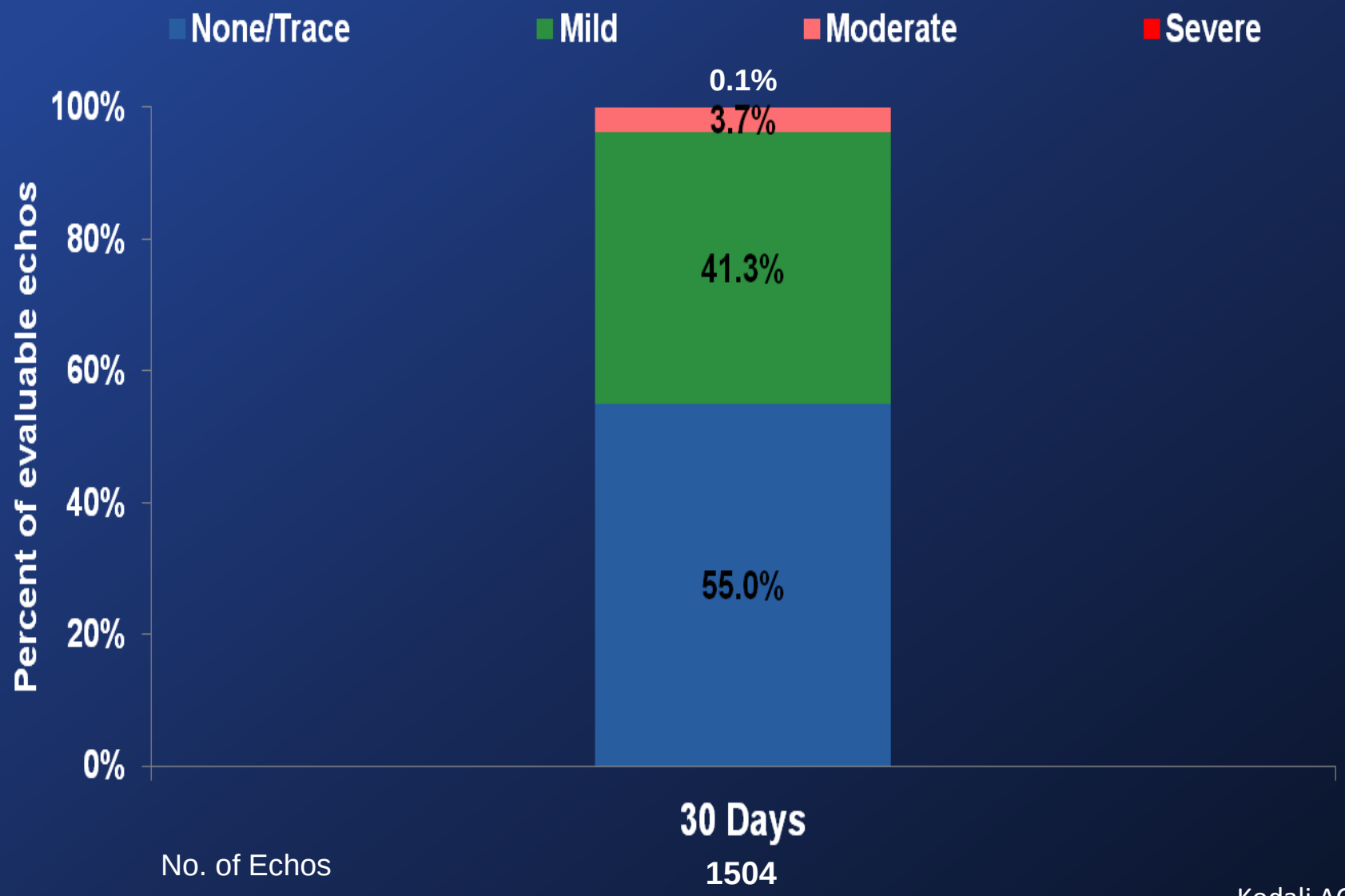
Strokes

At 30 Days (As Treated Patients)

Events (%)	S3HR Overall (n=583)	S3HR TF (n=491)	S3HR TA/TAo (n=92)	S3i Overall (n=1076)	S3i TF (n=951)	S3i TA/TAo (n=125)
All	1.54	1.63	1.09	2.60	2.42	4.00
Disabling*	0.86	0.81	1.09	1.02	0.95	1.60
Non-Disabling	0.69	0.81	0	1.58	1.47	2.40
TIA	0.69	0.61	1.09	0.37	0.42	0

**CEC adjudicated or Modified Rankin Score ≥ 2 at 30 days*

Paravalvular Leak: S3HR & S3i
(Valve Implant Patients)



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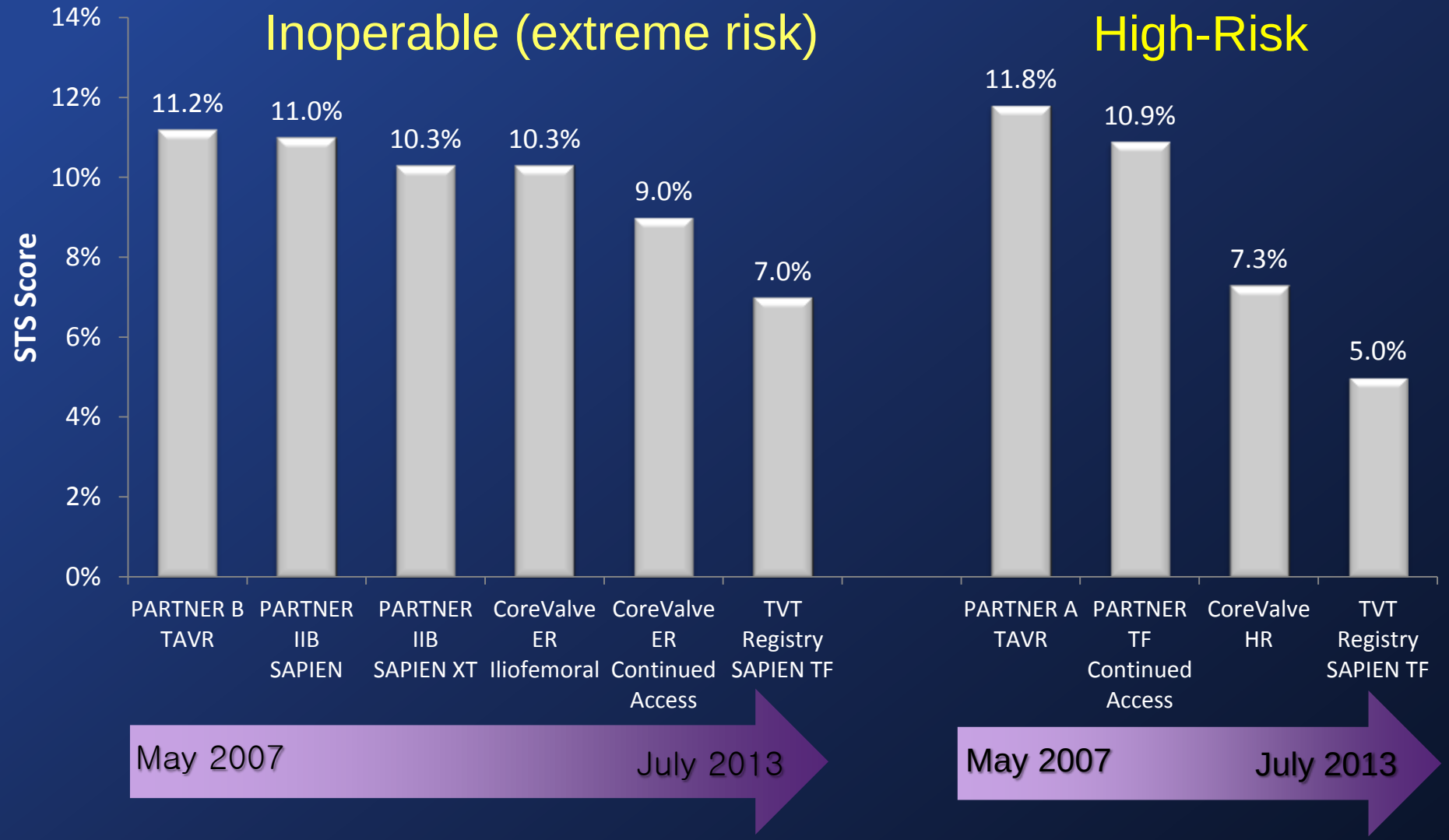
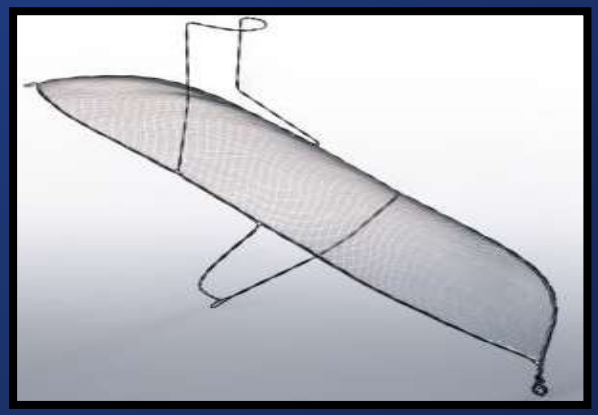
Evolution in Patient Selection in U.S. TAVR Clinical Trials



Cerebral Embolic Protection Devices

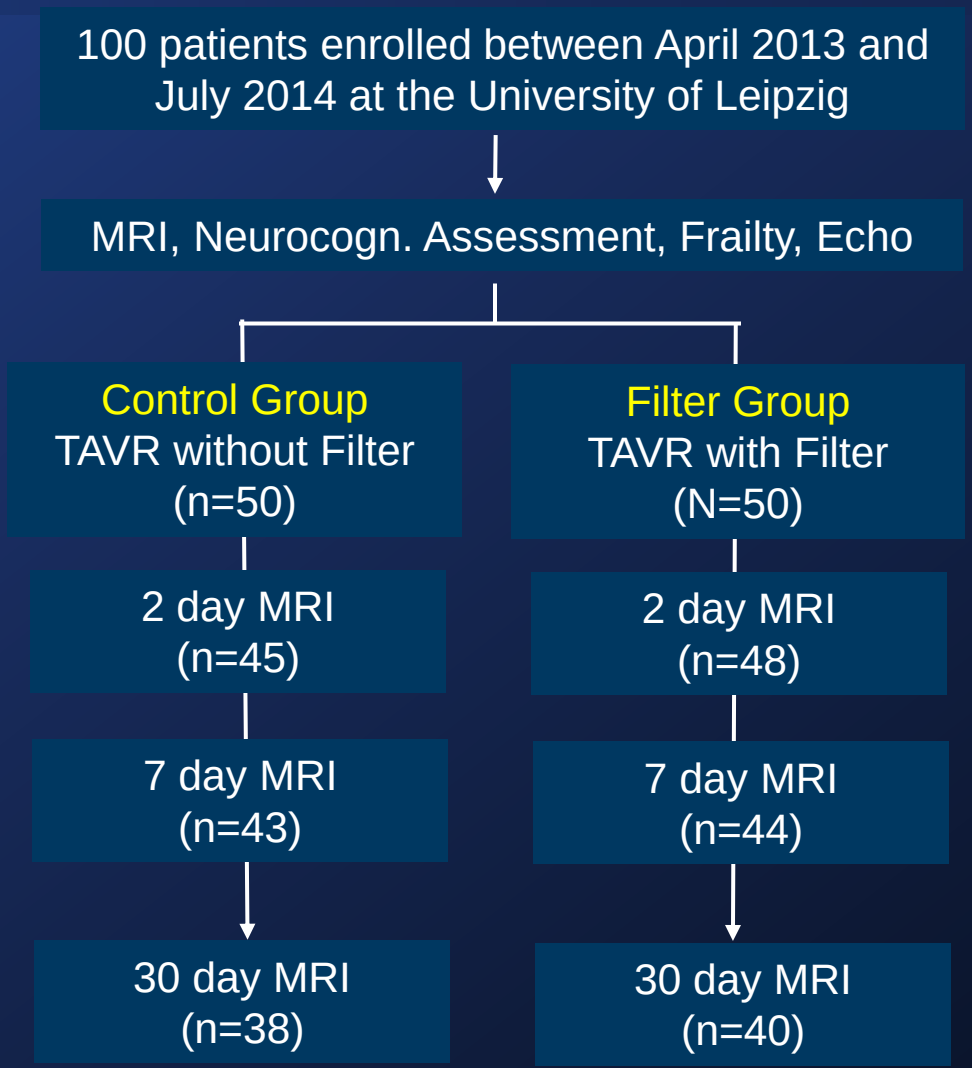
TriGuard Cerebral	Embrella	Claret Sentinel
Deflector	Deflector	Dual Filter
Femoral Access	Radial Access	Radial Access
9F Sheath (7F Delivery)	6F Shuttle Sheath	6F Radial Sheath



CLEAN - TAVI

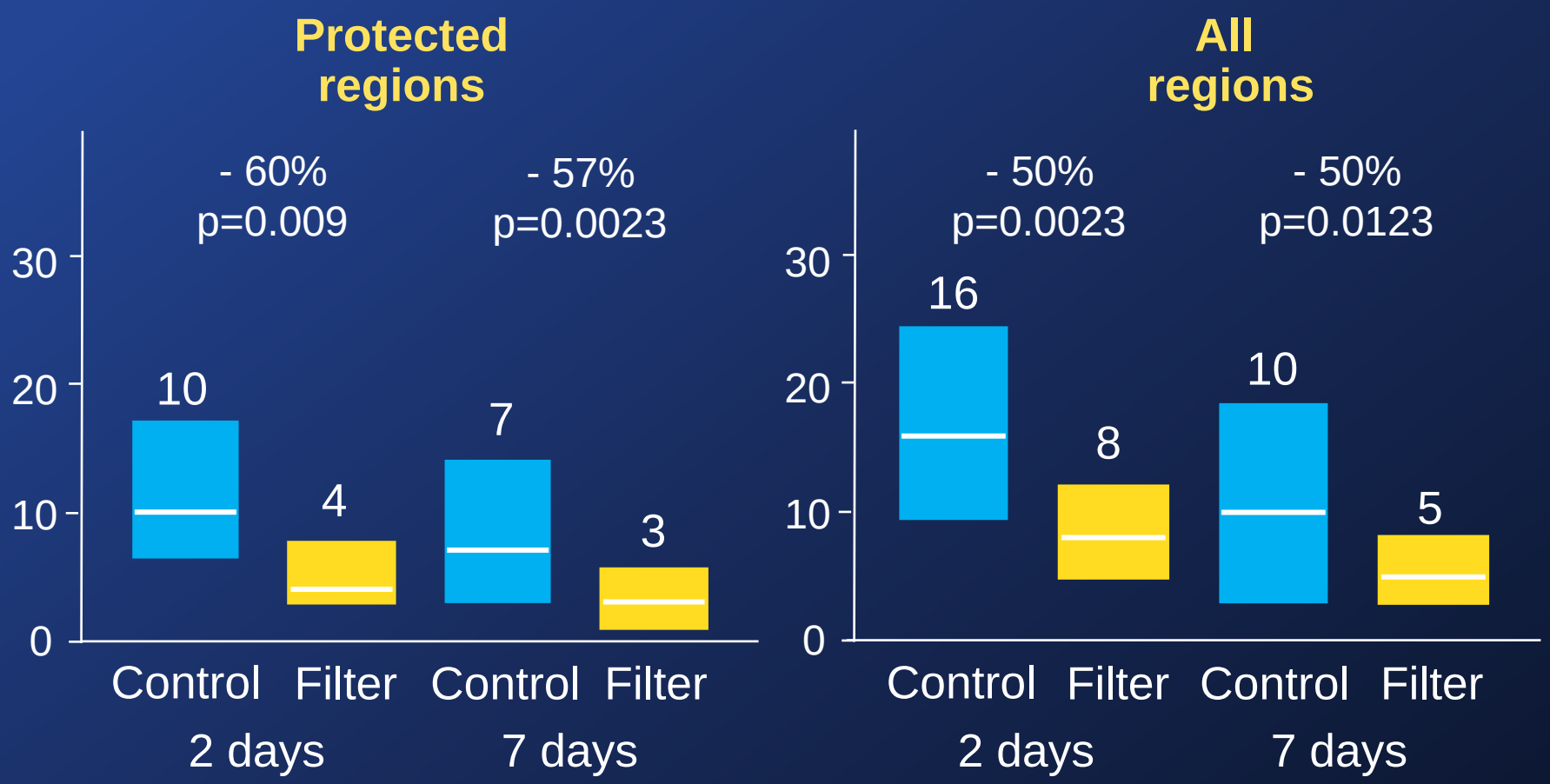
Design

- DESIGN: Prospective, randomized, double-blind single center study
- OBJECTIVE: To evaluate the impact of the Claret Montage™ on number of cerebral lesions in higher-risk patients with aortic stenosis udergoing TAVR with the MCV
- PRINCIPAL INVESTIGATOR
  Axel Linke, MD
  University of Leipzig,
  Heart Center, Germany



Linke et al., TCT 2014

Total Lesion Number at 2 & 7 days



The boxes identify the 25%-75% CI, the black lines and number represents the median.

Linke et al., TCT 2014

Future of TAVR