Current Status of Valvular and Structural Heart Disease Intervention in Japan: New Insights Form the OCEAN-SHD Family

Kentaro Hayashida MD, PhD, FESC, FACC, FJCS

Disclosure

A clinical proctor for Edwards Lifesciences, Medtronic, and Abbott

ICPS, Massy, France (2009-2012)

Massy Henri-Mondor registry

OCEAN-SHD family

	PERSONAL DATA				
	STUDY	last name	First nam	Date birth	Date
	REVIVE			4/10/20	11/10/06
	REVIVE			15/7/19	21/11/06
	REVIVE			27/4/19	21/11/06
				22/6/11	30/11/06
				27/8/13	5/12/06
				10/3/24	9/1/07
				2/3/23	6/2/07
	REVIVE			5/9/21	6/2/07
	REVIVE			8/9/26	13/2/07
	REVIVE			23/1/31	5/3/07
	REVIVE			17/2/28	6/3/07
	REVIVE			24/2/21	3/4/07
	REVIVE			4/1/19	23/5/07
	PARTNER			21/12/25	28/8/07
	PARTNER			18/3/30	30/8/07
	PARTNER			28/6/24	3/10/07

OCEAN-SHD family (Jan 2016, 8 centers)

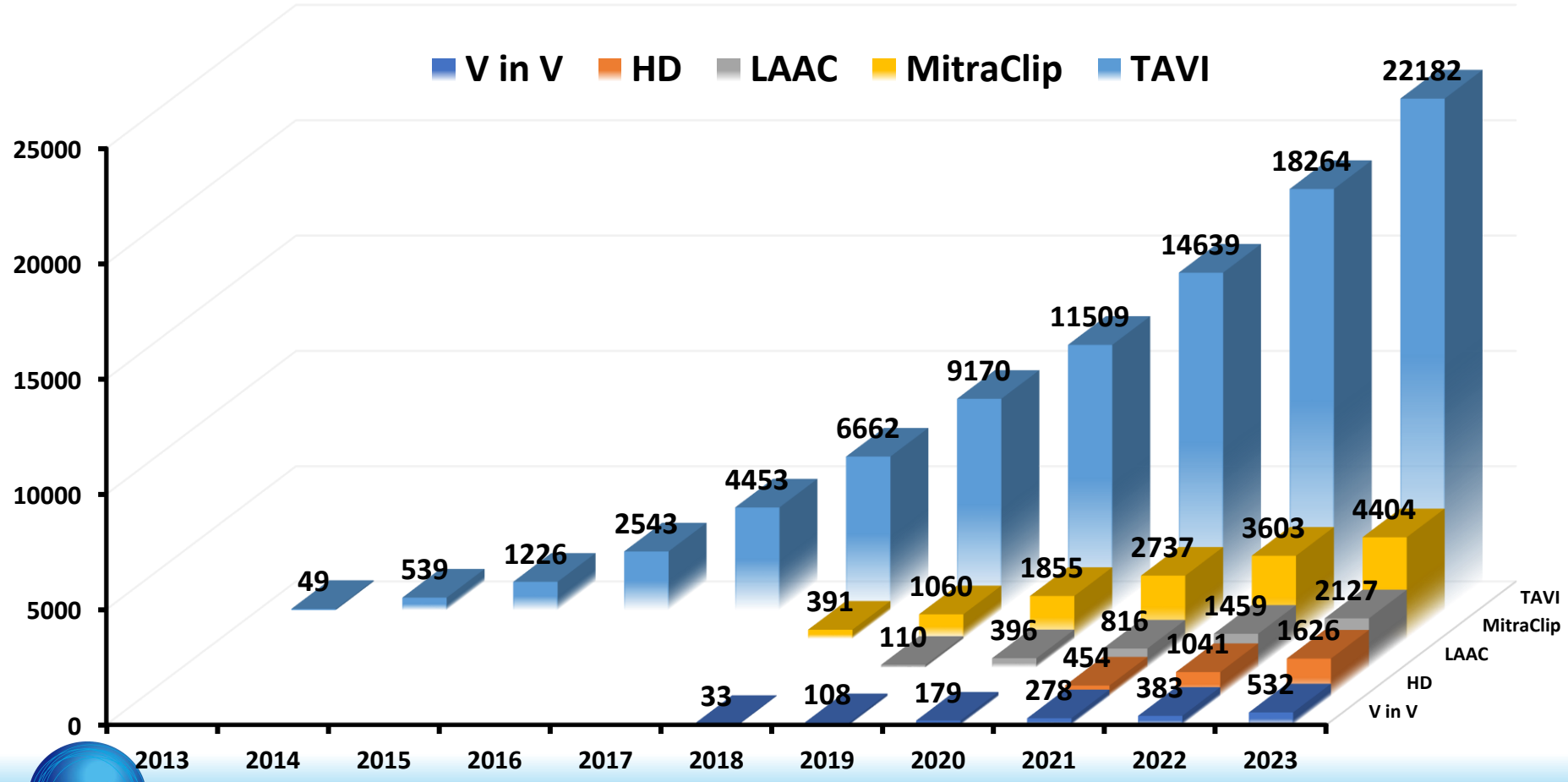
OCEAN-SHD family (Feb 2020, 25 centers)

The OCEAN-SHD family

The 10-year anniversary: The 21st January 2024

29 centers, 300 members in 2024

Annual number of SHD interventions in OCEAN



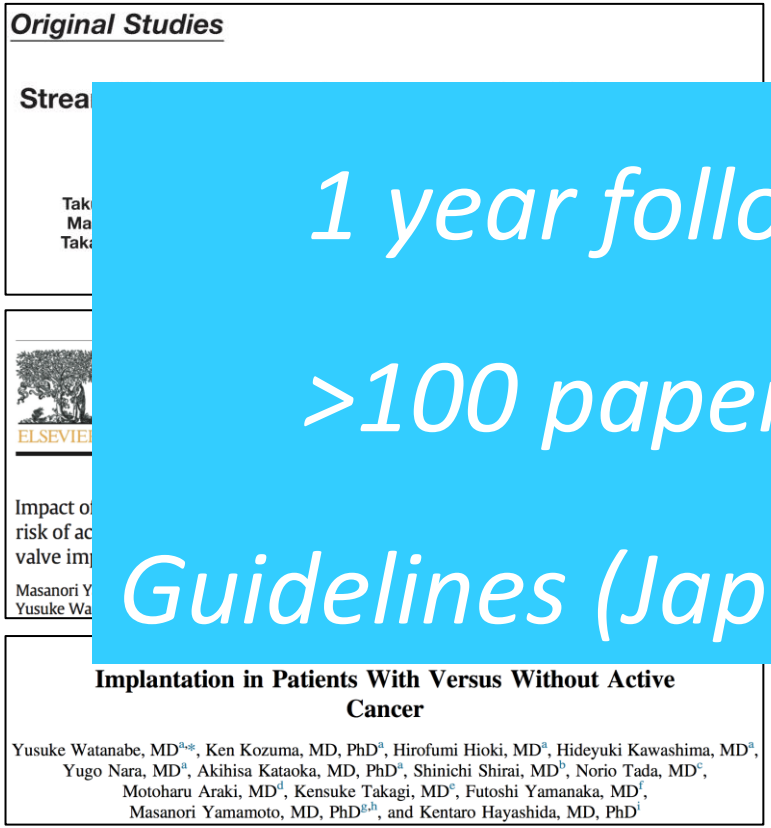
OCEAN-SHD
Optimised transCathEter aVAlvular interventIon
Structural Heart Disease

OCEAN-TAVI registry

1 year follow-up: 99%

>100 papers accepted

Guidelines (Japan, US, Europe)


Original Studies

Strea

Tak
Ma
Taka

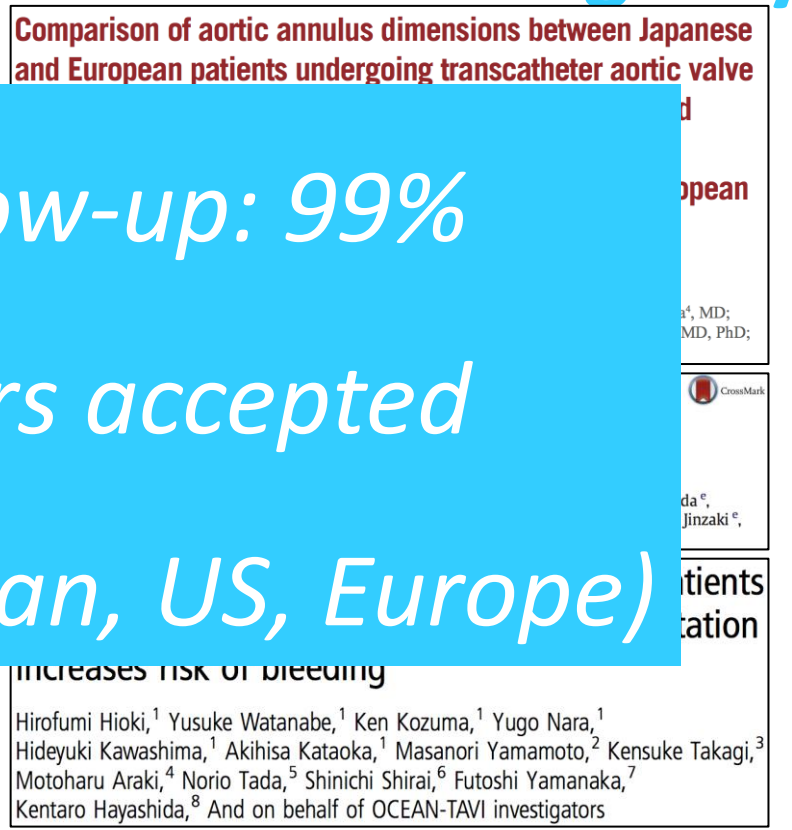
ELSEVIE

Impact o
risk of ac
valve imp

Masanori Y
Yusuke Wa

Implantation in Patients With Versus Without Active Cancer

Yusuke Watanabe, MD[a,*], Ken Kozuma, MD, PhD[a], Hirofumi Hioki, MD[a], Hideyuki Kawashima, MD[a], Yugo Nara, MD[a], Akihisa Kataoka, MD, PhD[a], Shinichi Shirai, MD[b], Norio Tada, MD[c], Motoharu Araki, MD[d], Kensuke Takagi, MD[e], Futoshi Yamanaka, MD[f], Masanori Yamamoto, MD, PhD[g,h], and Kentaro Hayashida, MD, PhD[i]


Comparison of aortic annulus dimensions between Japanese and European patients undergoing transcatheter aortic valve

d

opean

a[4], MD;
MD, PhD;

CrossMark

da [e],
Jinzaki [e],

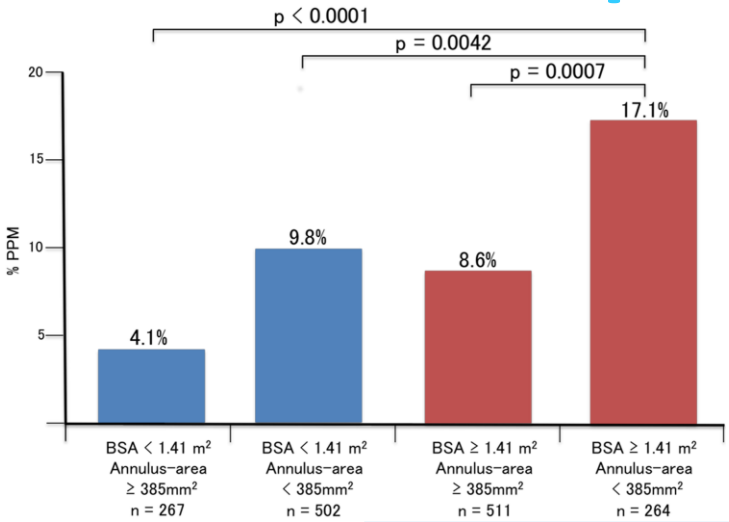
tients
tation

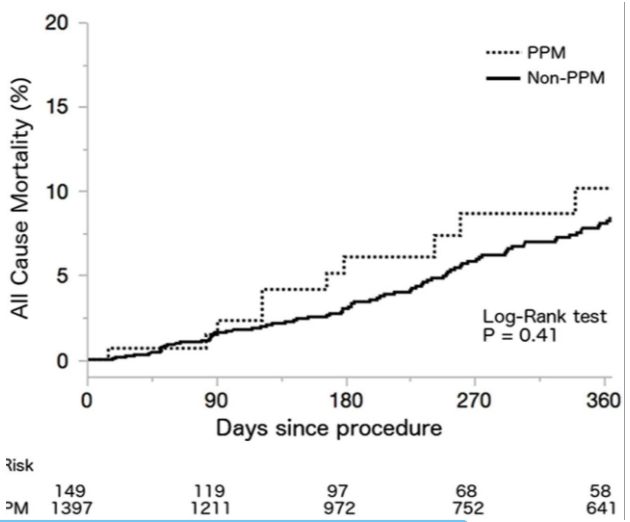
increases risk of bleeding

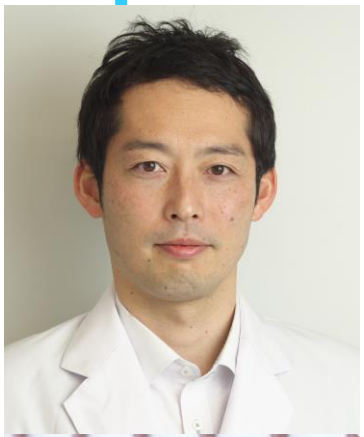
Hirofumi Hioki,[1] Yusuke Watanabe,[1] Ken Kozuma,[1] Yugo Nara,[1] Hideyuki Kawashima,[1] Akihisa Kataoka,[1] Masanori Yamamoto,[2] Kensuke Takagi,[3] Motoharu Araki,[4] Norio Tada,[5] Shinichi Shirai,[6] Futoshi Yamanaka,[7] Kentaro Hayashida,[8] And on behalf of OCEAN-TAVI investigators

OCEAN-SHD
Optimised transCatheter aVAlvular interventIon
Structural Heart Disease

Low prevalence of PPM in Japan







moderate PPM: 8.9% (138)

severe PPM: 0.7% (11)

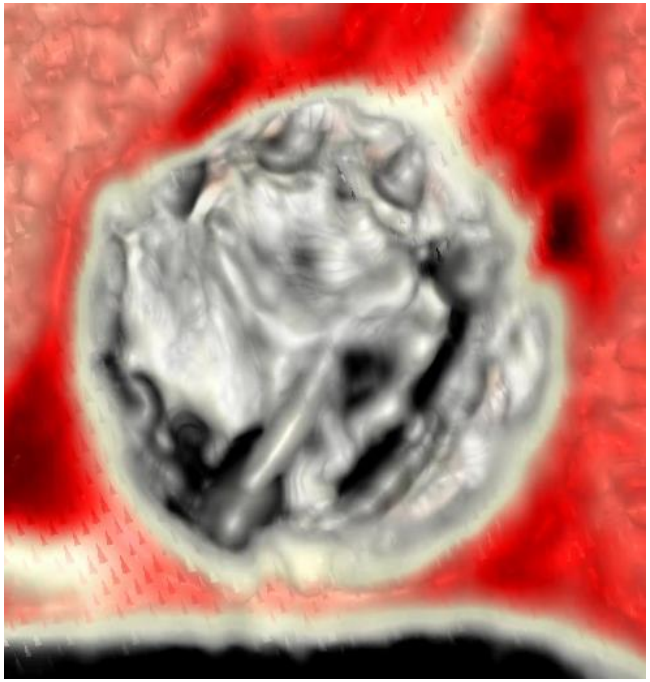
*12% in US**

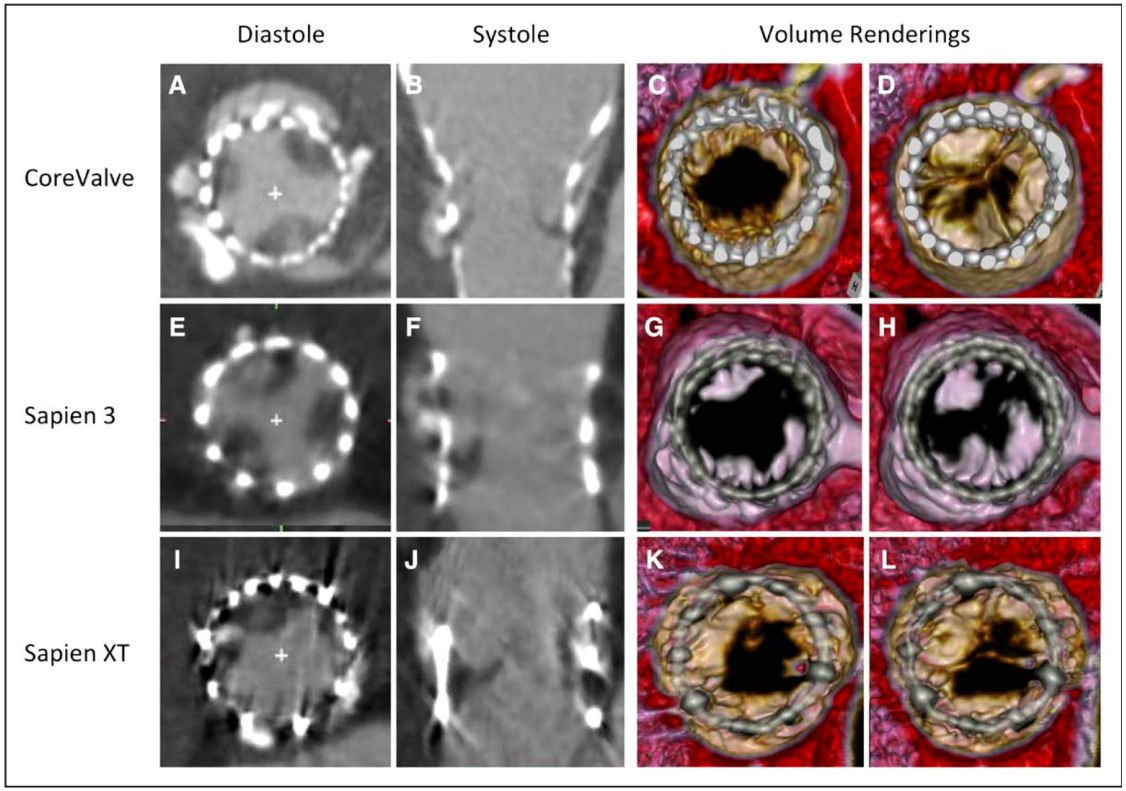
mean BSA: 1.4m² (JP) vs. 1.9m² (US)

OCEAN-SHD

*Miyasaka, Tada et al. JACC Int in 2017, Herman et al. JACC 2018**

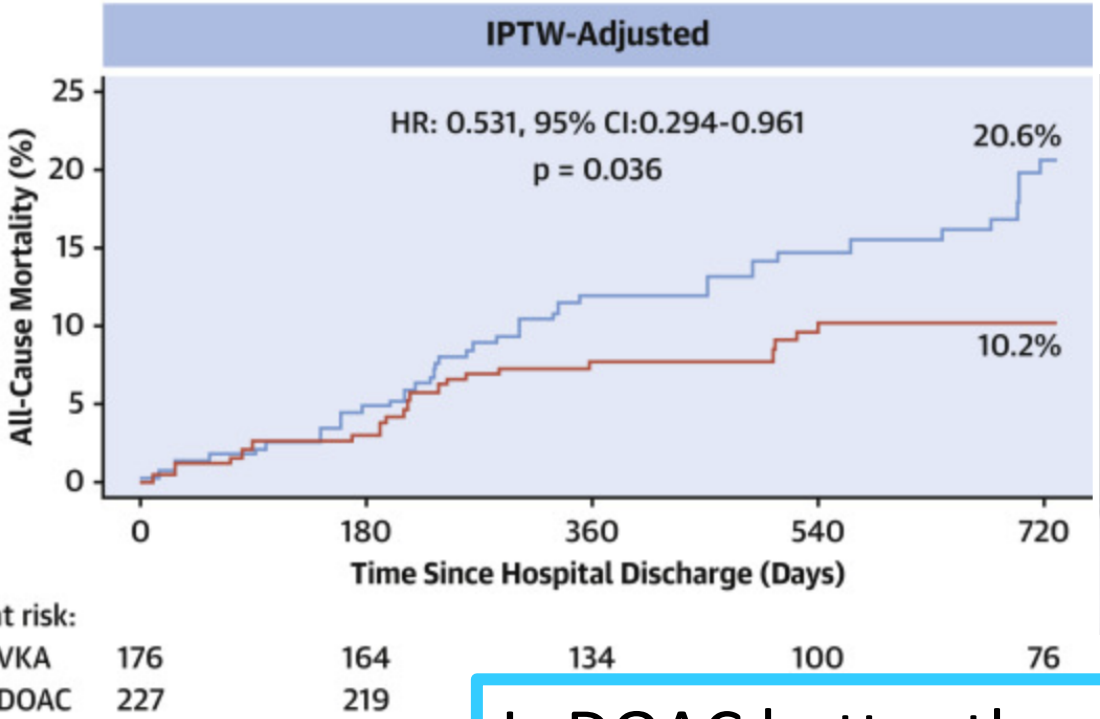
Leaflet thrombosis (OCEAN-TAVI)





Yanagisawa et al. Circ Cardiovasc Interv. 2019

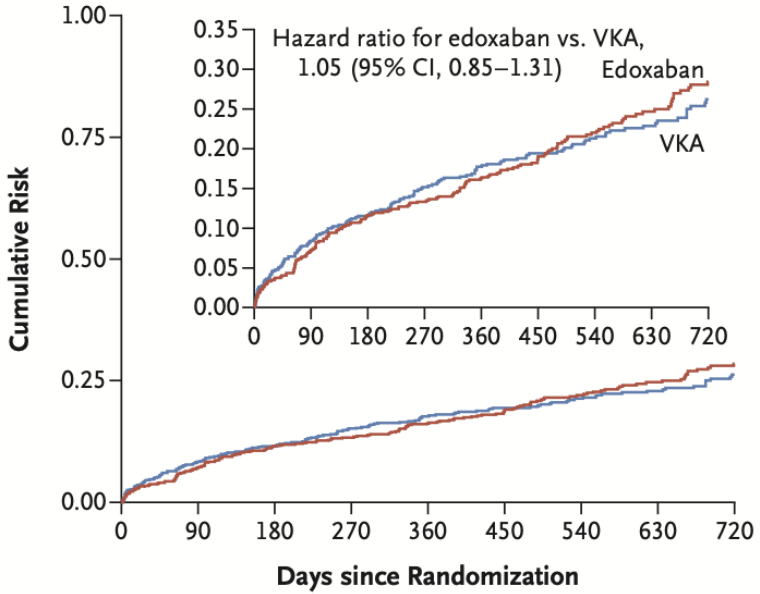
DOAC vs. VKA after TAVI for patients with Af



Is DOAC better than Warfarin?

Kawashima, Watanabe et al. JACC Cardiovasc Interv. 2020

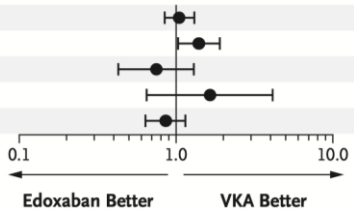
ENVISAGE-TAVI AF trial



No. at Risk

Edoxaban	713	618	568	543	504	410	332	245	181
VKA	713	597	545	510	474	387	322	247	175

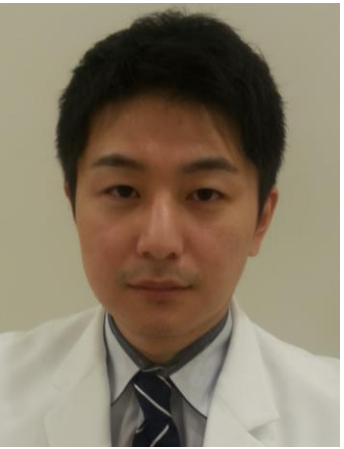
Event	Edoxaban	VKA
	rate per 100 person-yr (no. of patients/total no.)	
Net adverse clinical events	17.3 (170/713)	16.5 (157/713)
Major bleeding	9.7 (98/713)	7.0 (68/713)
Ischemic stroke	2.1 (22/713)	2.8 (28/713)
Myocardial infarction	1.1 (12/713)	0.7 (7/713)
Death from any cause	7.8 (85/713)	9.1 (93/713)



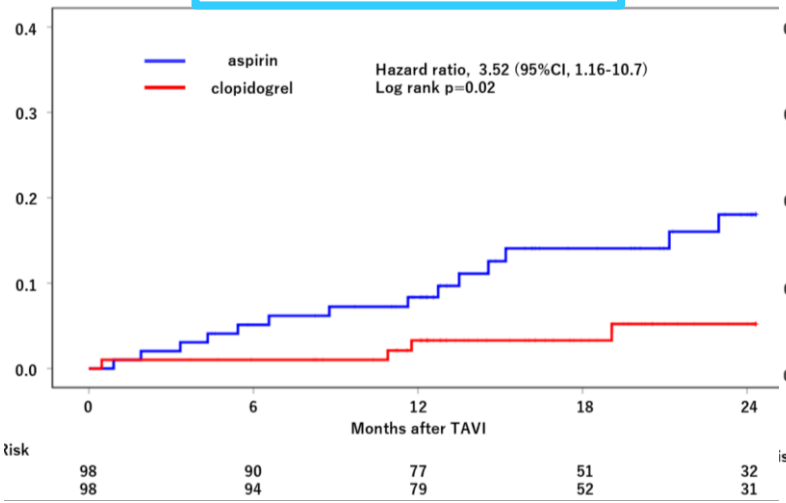
Edoxaban noninferior to Warfarin

NEJM 2021

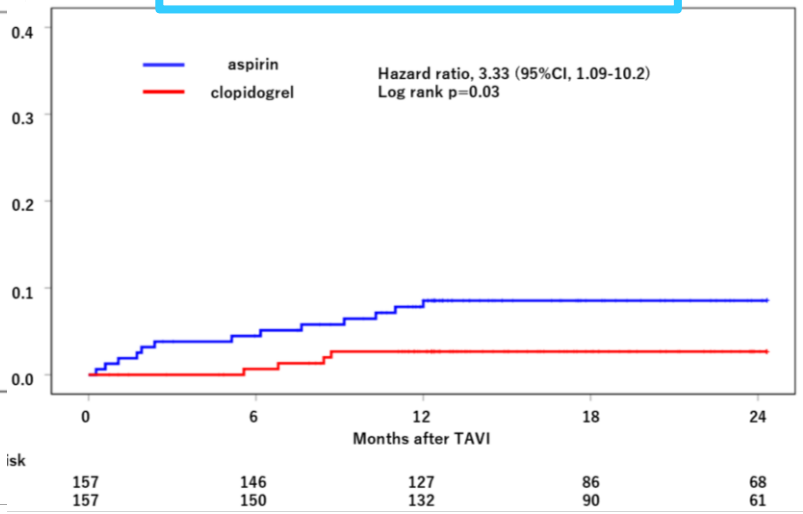
Clopidogrel is better that ASA to reduce cardiovascular death after TAVI



With anticoagulation



Without anticoagulation

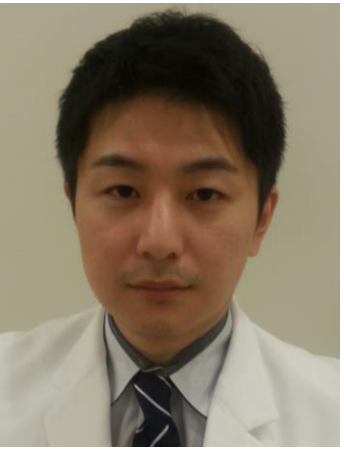


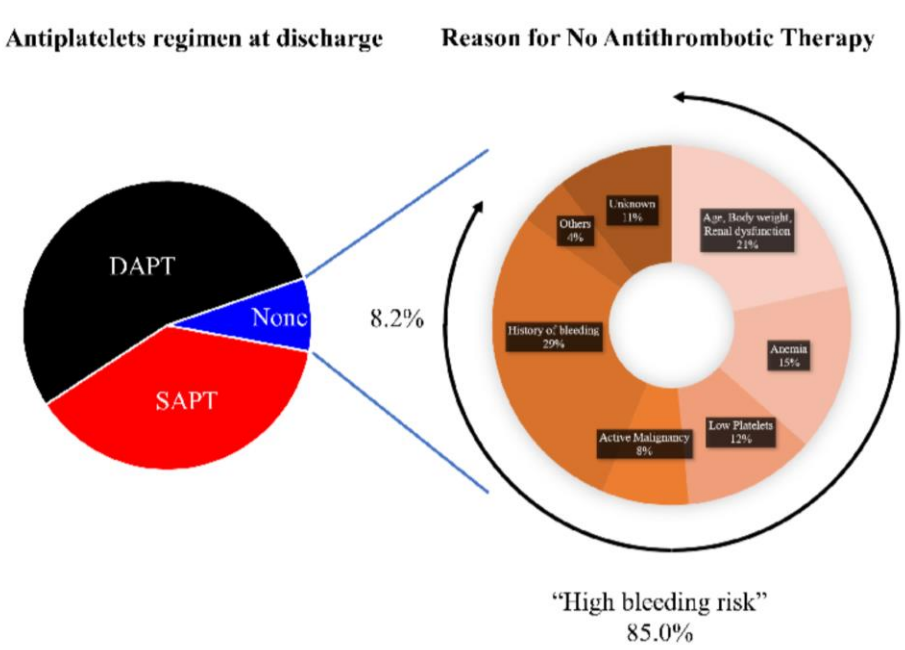
Clopidogrel was better than ASA

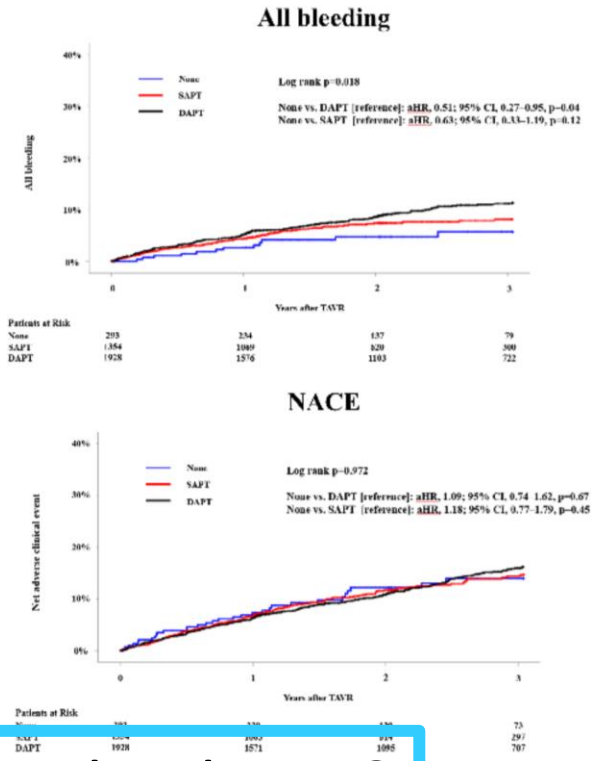
OCEAN-SHD

Kobari et al. Circulation Cardiovasc Interv. 2021

No antithrombotic regimen after TAVI







We do not need an antiplatelet Tx?

Kobari et al. JACC Interv. 2023

RCT by the OCEAN-SHD family

- No APT (n=180) vs. ASA (n=180) after TF-TAVI
- Multicenter RCT (20 centers)

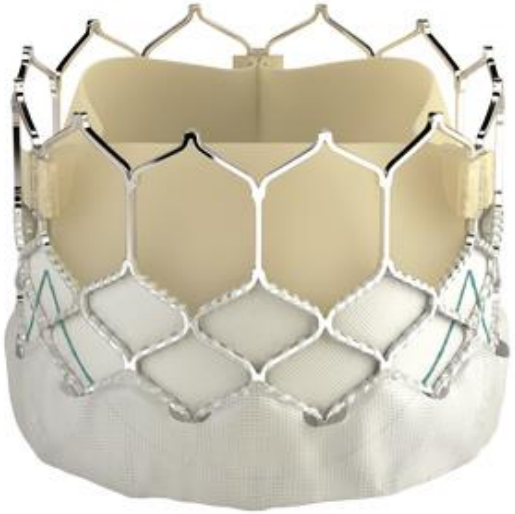
NAPT trial

Non-**A**ntithrombotic thera**P**y after **T**ranscatheter aortic valve implantation - trial

OCEAN-SHD
Optimised transCathEter sHvalvular interventIon
Structural Heart Disease

Currently available TAVR devices in Japan

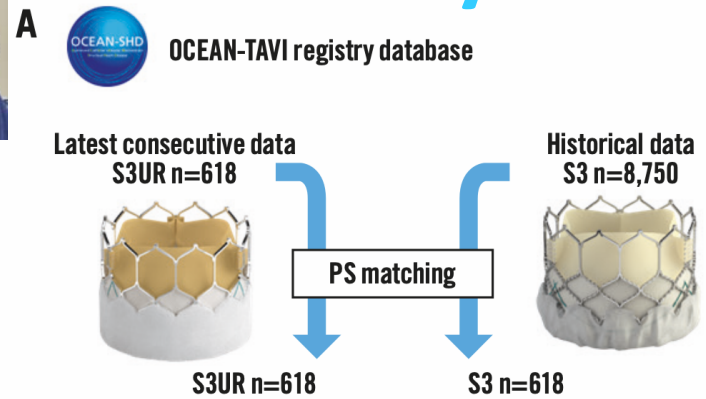
Sapien 3
Ultra RESILIA

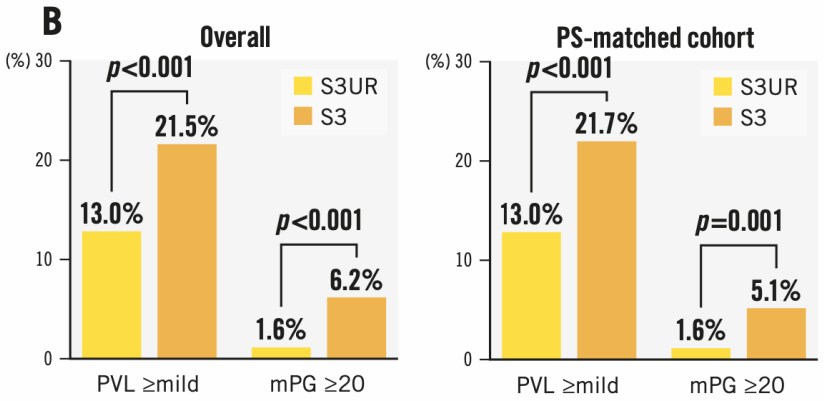


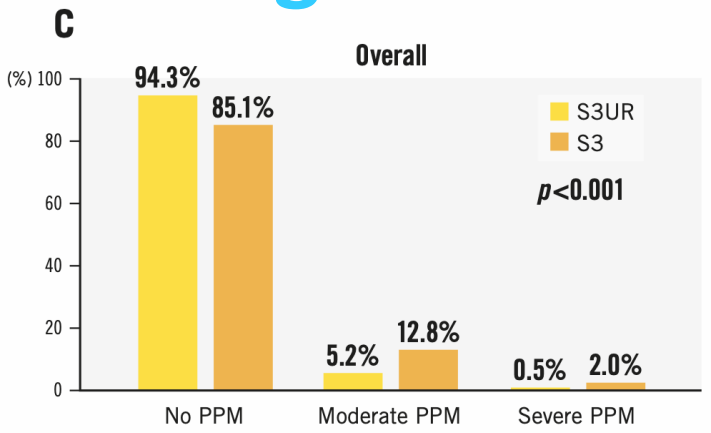
Evolut FX

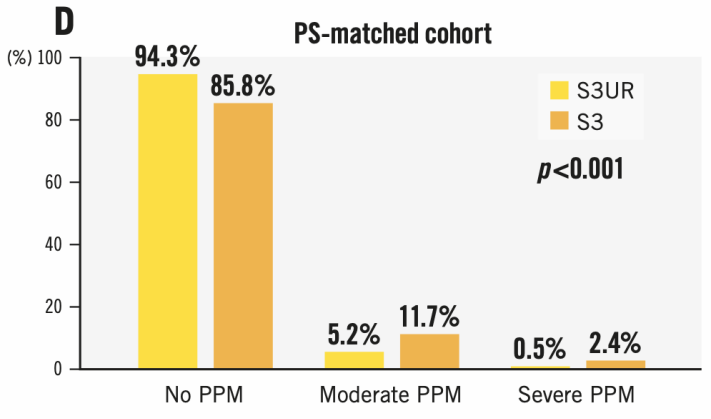
Navitor vision

Hemodynamic advantage of S3UR







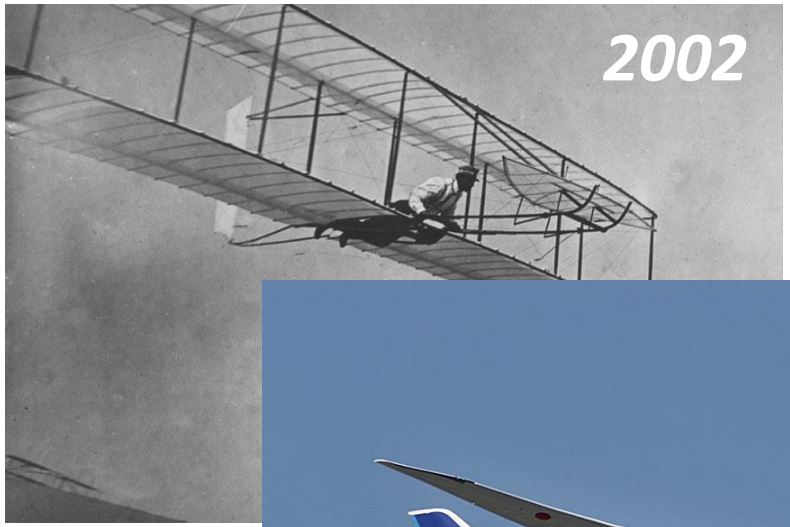


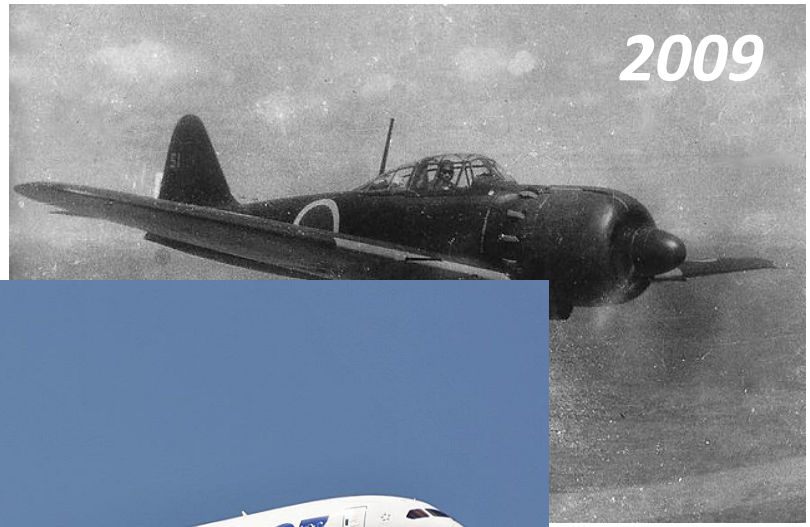
Yamamoto et al. EuroIntervention 2024

Top 11 citation from OCEAN-TAVI

1	Shimura	Clinical frailty scale	Circulation	2017	251	41.8
2	Yanagisawa	HALT	Circ Interv	2019	97	24.3
3	Watanabe	Active cancer	AJC	2016	87	12.4
4	Watanabe	RBBB	JACC Interv	2016	84	12
5	Miyasaka	PPM	JACC Interv	2018	77	15.4
6	Yamamoto	hypoalbuminemia	AJC	2017	76	12.7
7	Yamamoto	Coronary protection	IJC	2016	74	10.6
8	Ochiai	Renin-Angiotensin	Heart	2018	71	14.2
9	Kano	Gait speed	Circ Interv	2017	69	11.5
10	Kawashima	DOAC	JACC Interv	2020	65	21.6
11	Hioki	Pre DAPT	Heart	2017	60	10

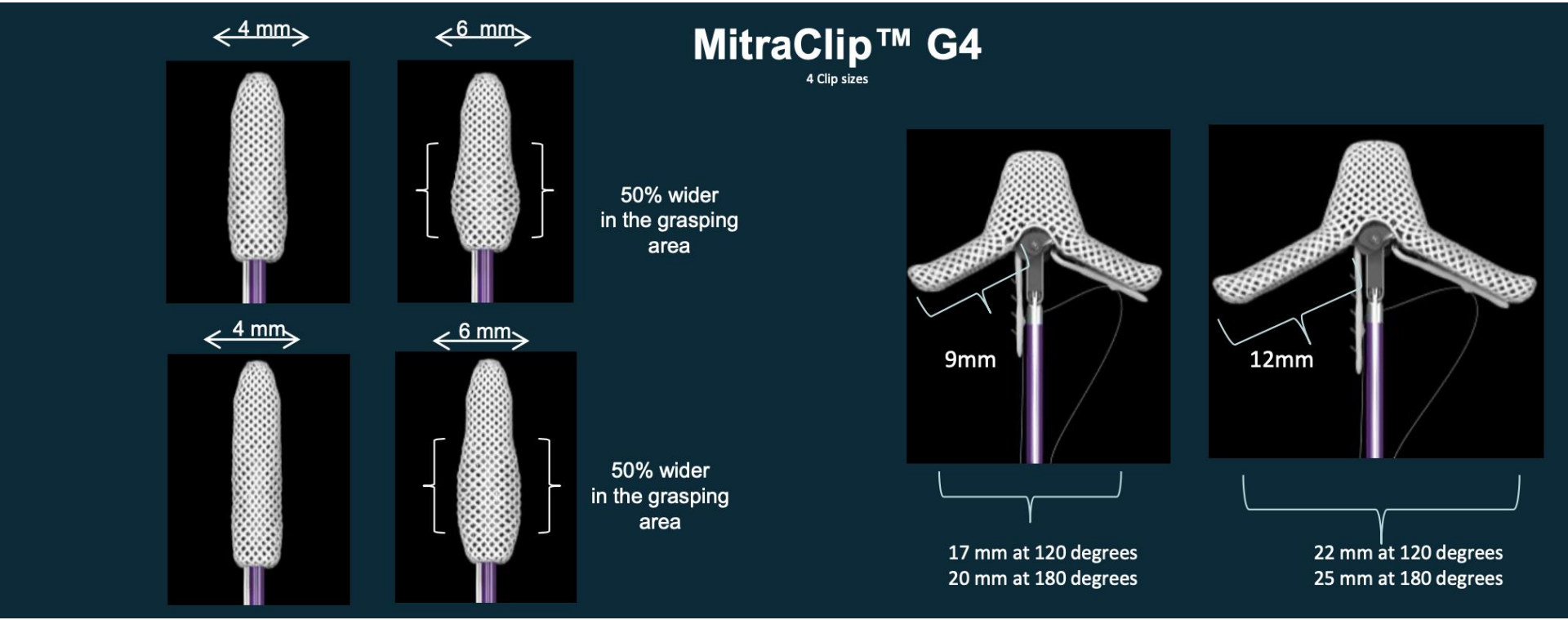
Past, present and future





Keio University
1858
CALAMVS GLADIO FORTIOR

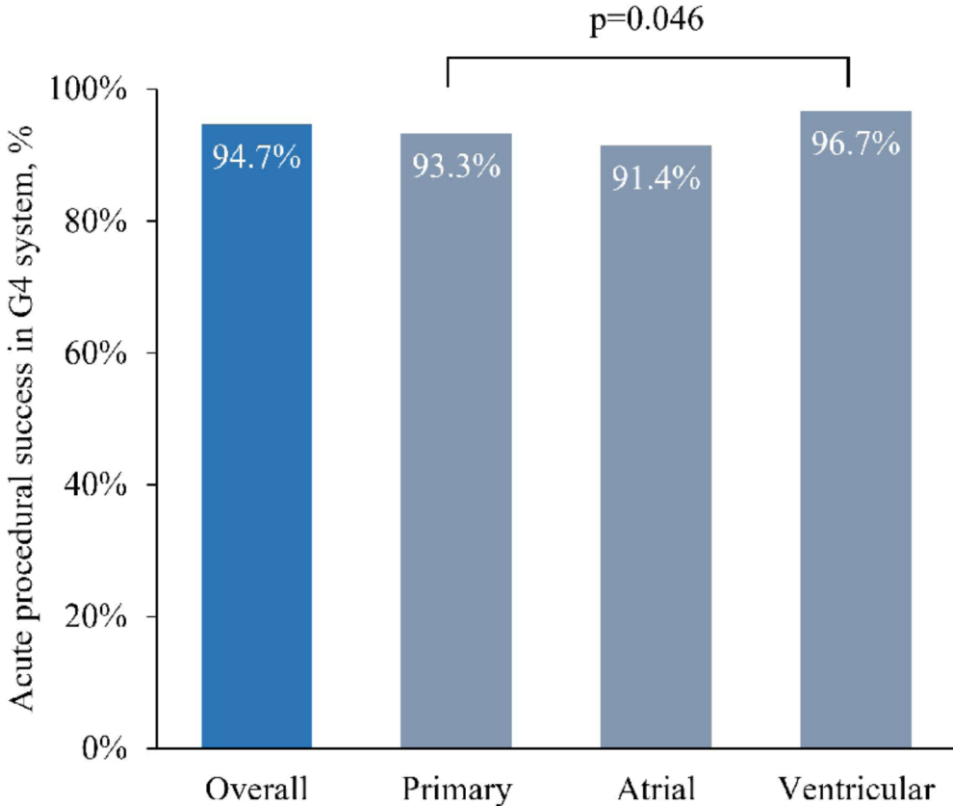
MitraClip G4



2020/9/1-

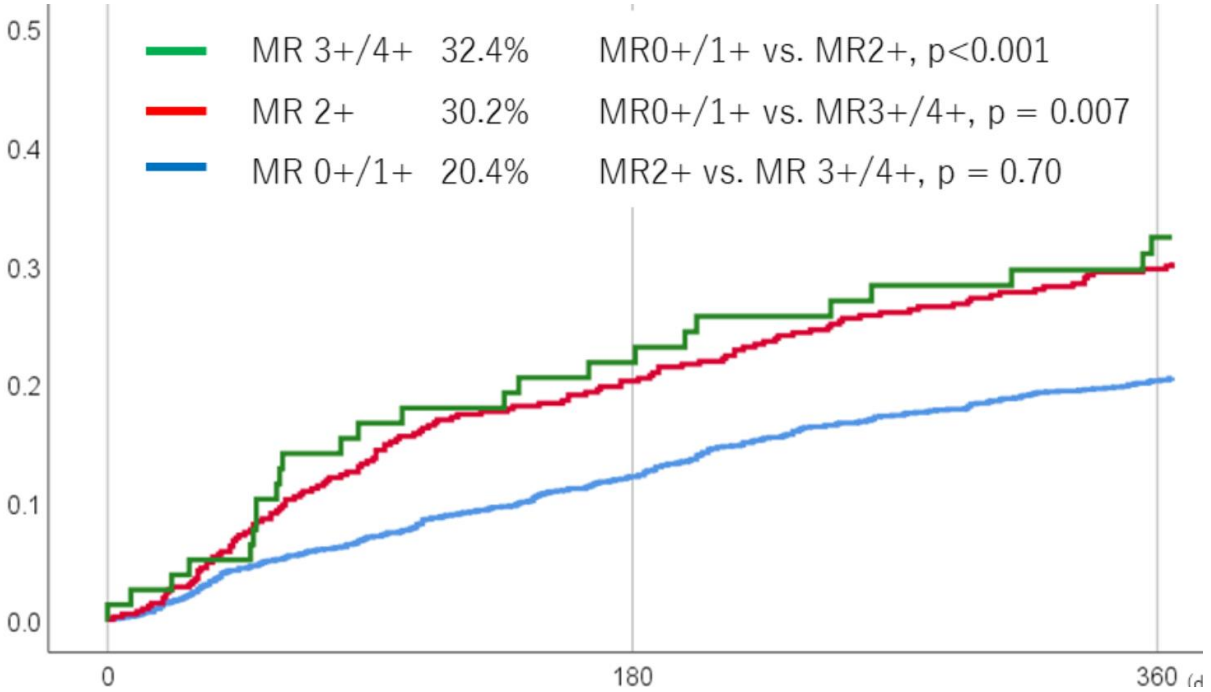
Keio University
1858
CALAMVS GLADIO FORTIOR

OCEAN-Mitral 30-day outcome



Saji et al. JACC Asia 2023

OCEAN-Mitral: 1-year outcome



Kubo et al. JAHA 2023

PASCAL Repair System

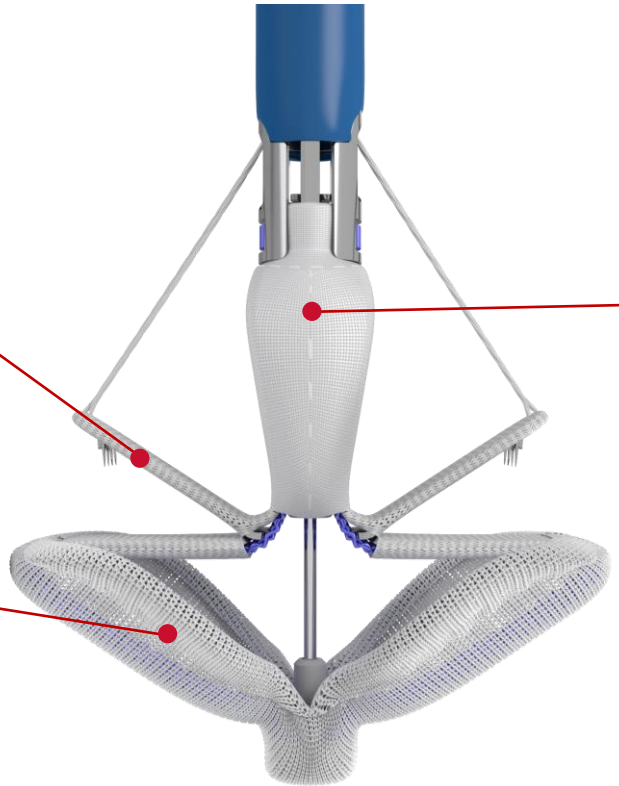
Implant

CLASPS

- Allows for staged leaflet capture and adjustment of leaflet insertion
- Contains retention elements

PADDLES

- Approximates leaflets
- Curvature designed to reduce stress on native leaflets

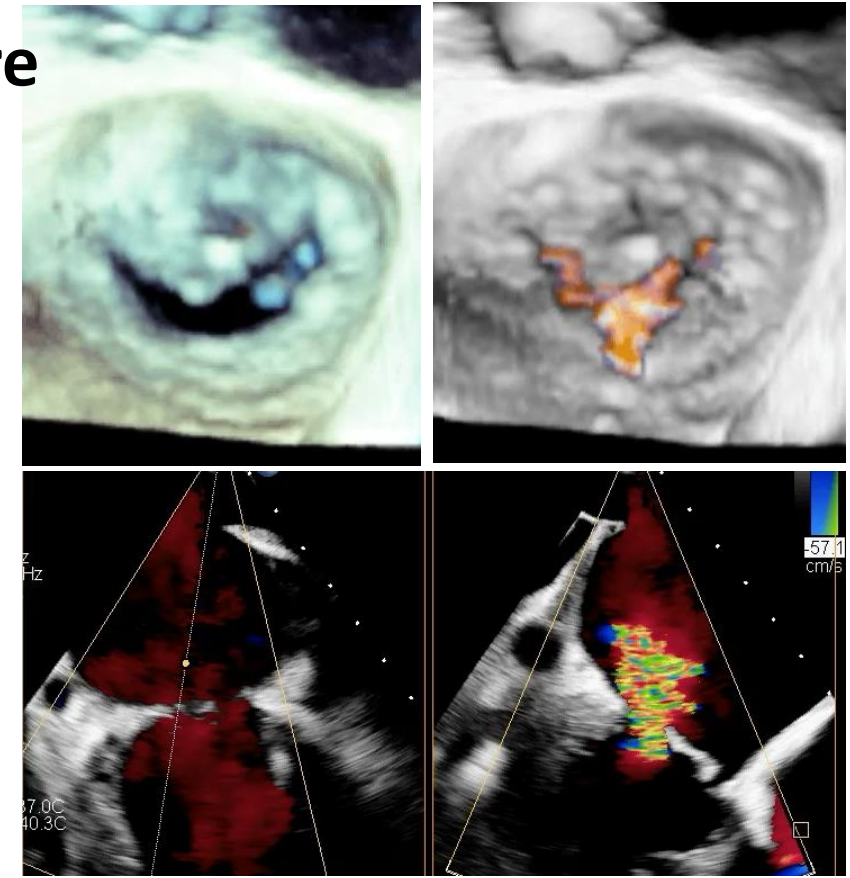


SPACER

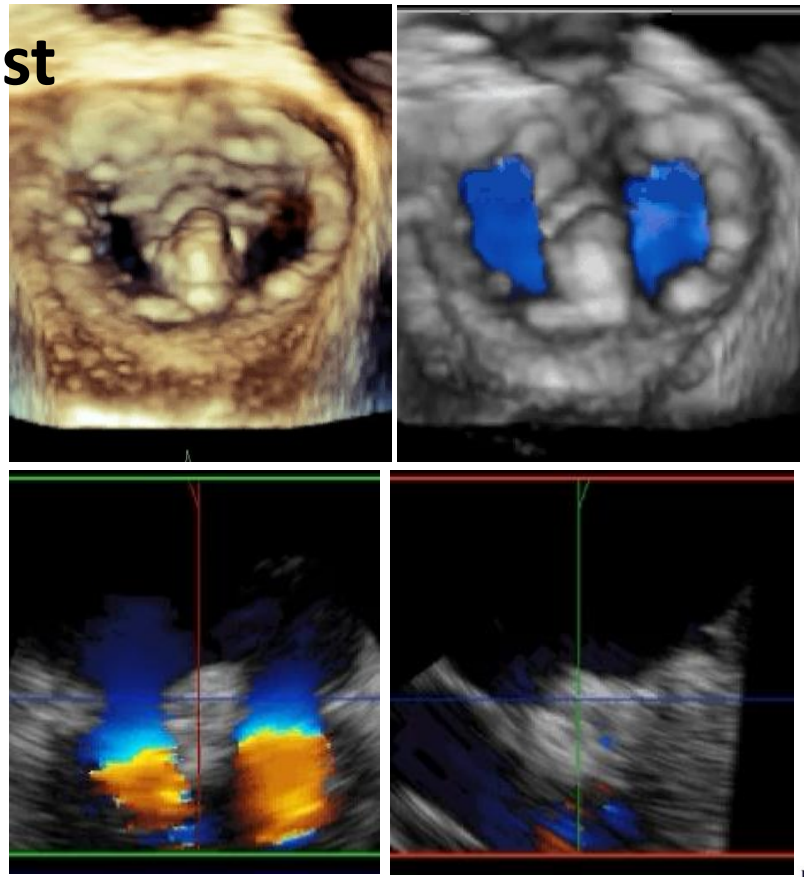
- Fills regurgitant orifice area
- Reduces leaflet approximation distance

PASCAL P10 for atrial FMR

Pre



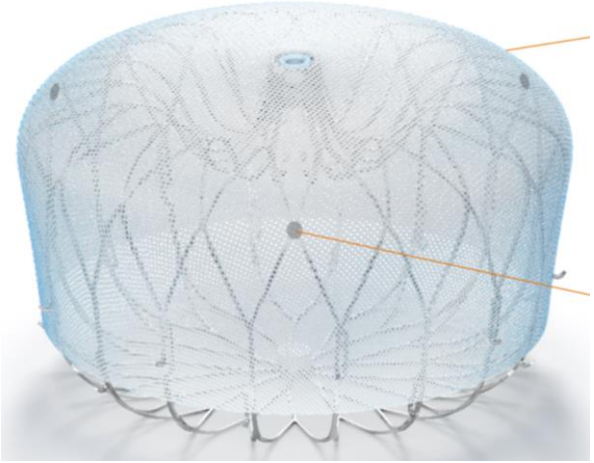
Post



Keio University
1858
CALAMVS GLADIO FORTIOR

Devices for LAAC in Japan

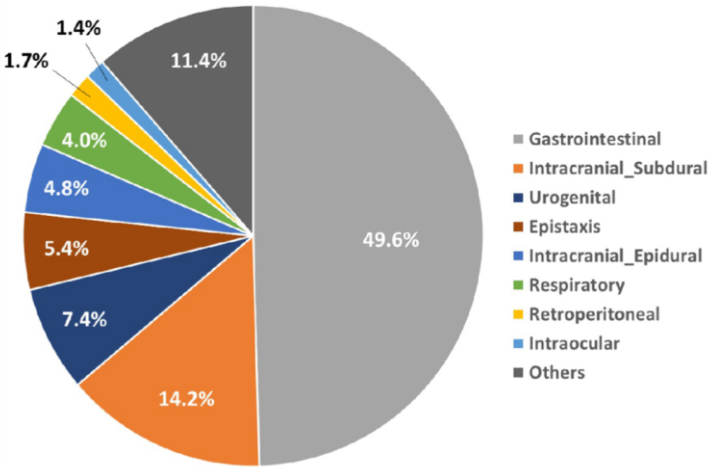
Watchman FLX, Boston Scientific



Amulet, Abbott

The OCEAN-LAAC registry

History of bleeding



The OCEAN-LAAC registry (n = 548)
Mean $CHADS_2$ score of 3.1 ± 1.3, CHA_2DS_2-VASc score of 4.7 ± 1.5, and HAS-BLED score of 3.2 ± 1.0 points
Device success: 96.5% **Technical success:** 96.0% **Procedural success:** 90.5%

Anticoagulants cessation at 45-day follow-up: 89.9%

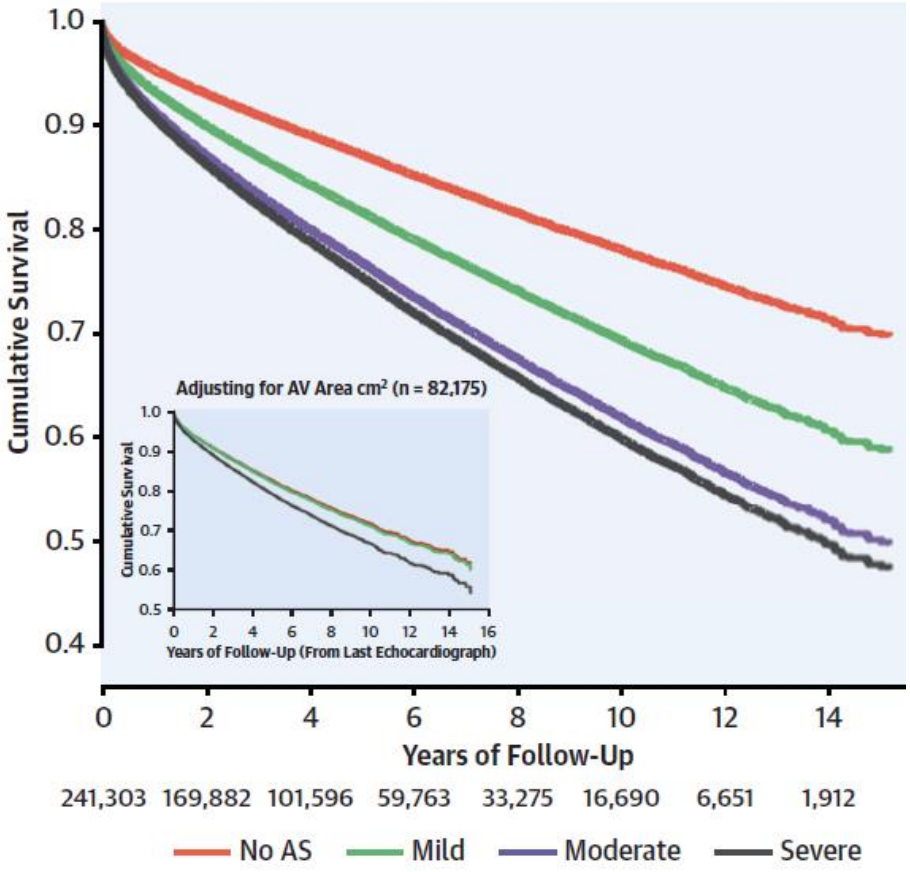
	Younger group (age ≤70) n = 104	Middle-aged group (70< age ≤80) n = 271	Elderly group (80< age) n = 173
	In-hospital/at 45-day	In-hospital/at 45-day	In-hospital/at 45-day
All-cause death	0.0%/1.0%	0.0%/0.4%	0.0%/0.0%
Any strokes	0.0%/0.0%	0.0%/0.7%	0.0%/0.0%
Any bleedings	1.9%/5.8%	1.5%/5.9%	4.6%/10.4%
Pericardial effusions	1.0%/1.0%	1.5%/1.5%	3.5%/4.6%
Device embolization	0.0%/0.0%	0.0%/0.0%	0.0%/0.0%

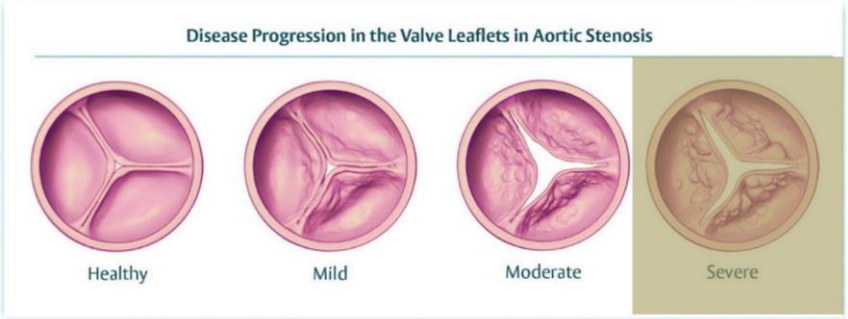


Asami et al. JACC Asia 2023

Keio University
1858
CALAMVS GLADIO FORTIOR

Natural history of moderate AS





Prognosis of moderate AS is similar to severe AS?

Strange G, Stewart S, Celermajer D, et al. Poor long-term survival in patients with moderate aortic stenosis.
Journal of the American College of Cardiology. 2019;74(15):1851-1863.

Keio University
1858
CLARVS GLADIO FORTIOR

Moderate AS

THE PROGRESS TRIAL

Local heart team, case review board & core lab assessments

↓

Moderate aortic stenosis, cardiac damage/dysfunction,
anatomy appropriate for transfemoral access

↓

1:1 Randomization
(up to 750 patients)

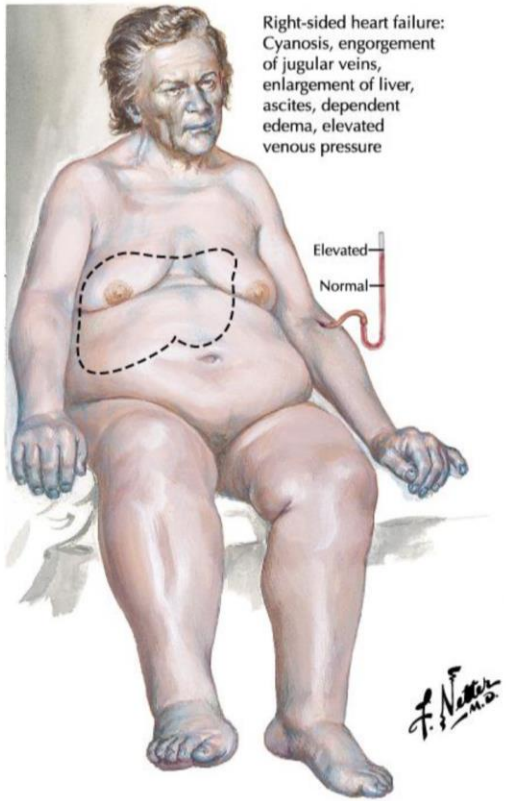
TAVR	vs.	Clinical surveillance
(SAPIEN 3 platform)		*(until guideline-recommended criteria for the timing of AS intervention is met)*

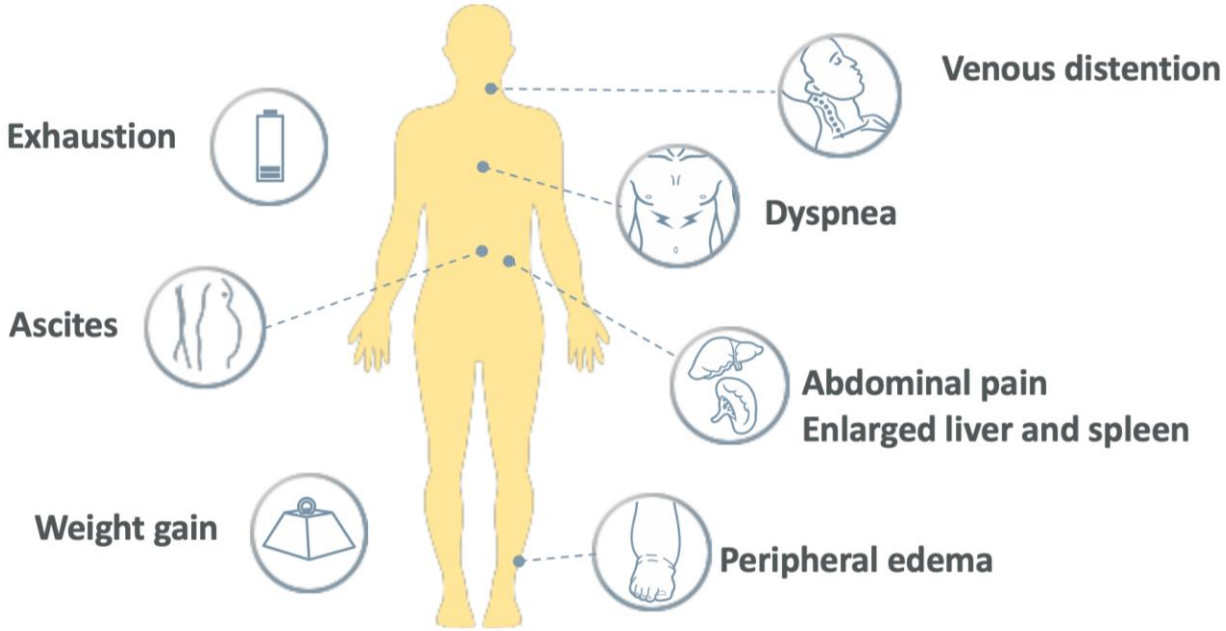
Primary Endpoints:
Effectiveness: Non-hierarchical composite of death, and heart failure (HF) hospitalization or event at 2 years
Safety: Non-hierarchical composite of death, stroke, life-threatening bleeding and other events at 30 days

Follow-up: 30 days then annually through 10 years

Keio University
1858
CALAMVS GLADIO FORTIOR

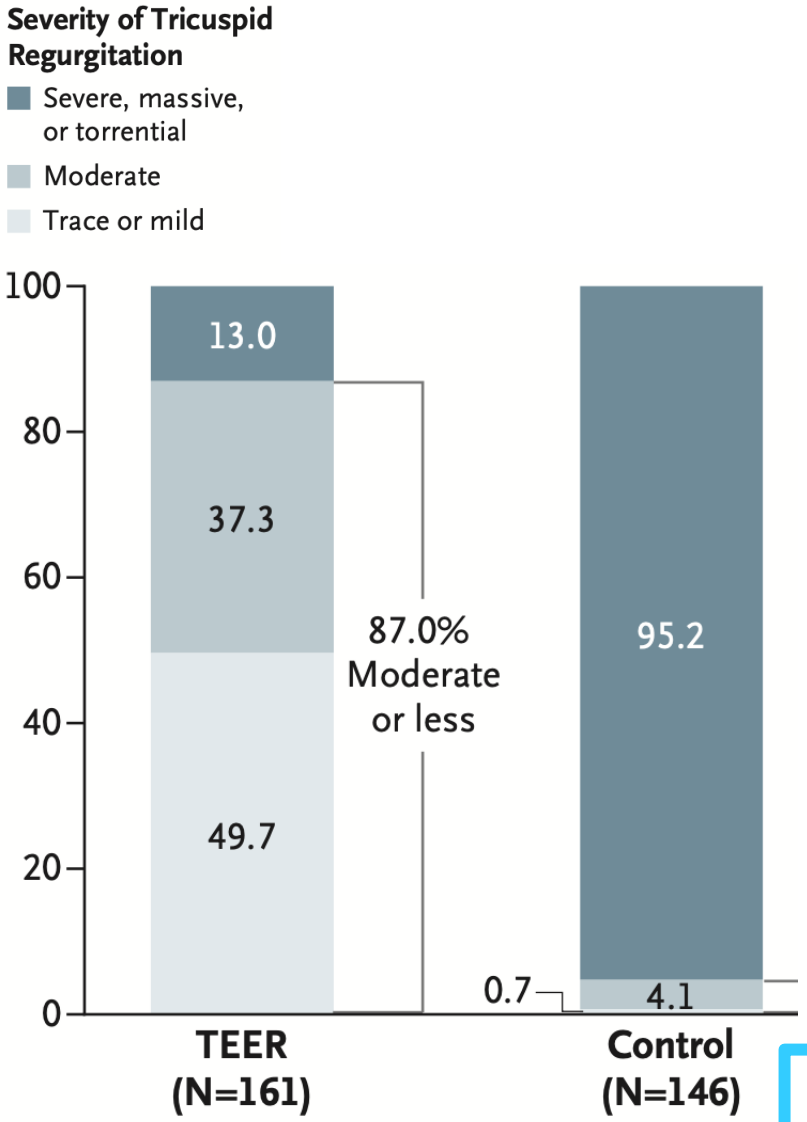
Tricuspid regurgitation





Keio University
1858
CALAMVS GLADIO FORTIOR

TRILUMINATE study



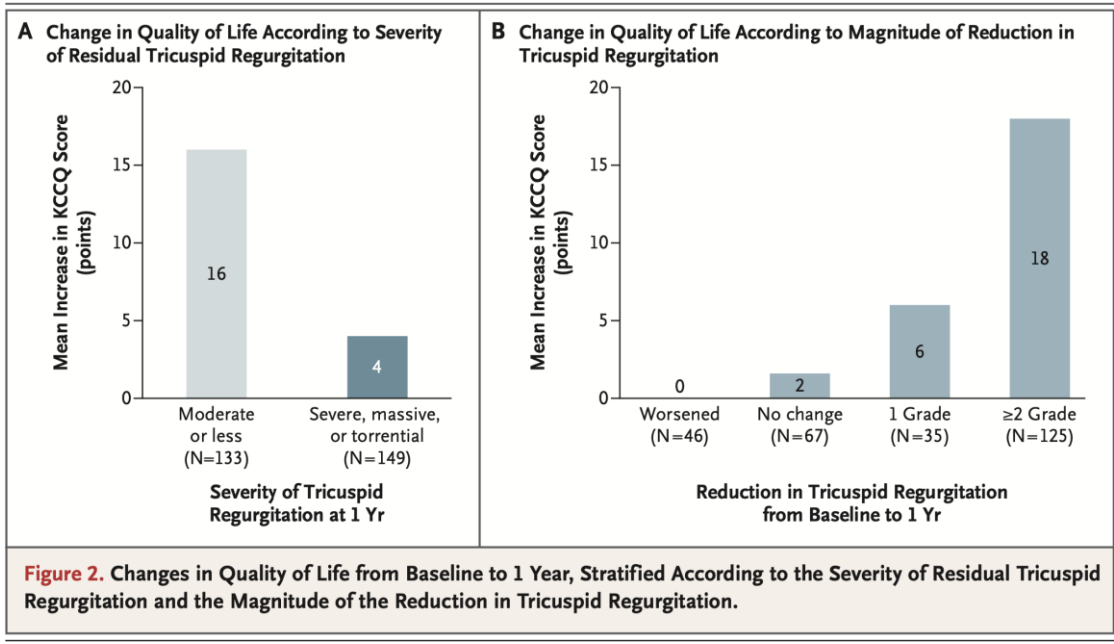


Figure 2. Changes in Quality of Life from Baseline to 1 Year, Stratified According to the Severity of Residual Tricuspid Regurgitation and the Magnitude of the Reduction in Tricuspid Regurgitation.

Improvement of QOL

ACC 2023

Sorajja et al. NEJM 2023

Keio University
1858
CALAMVS GLADIO FORTIOR

TriClip™ G4 TVRS

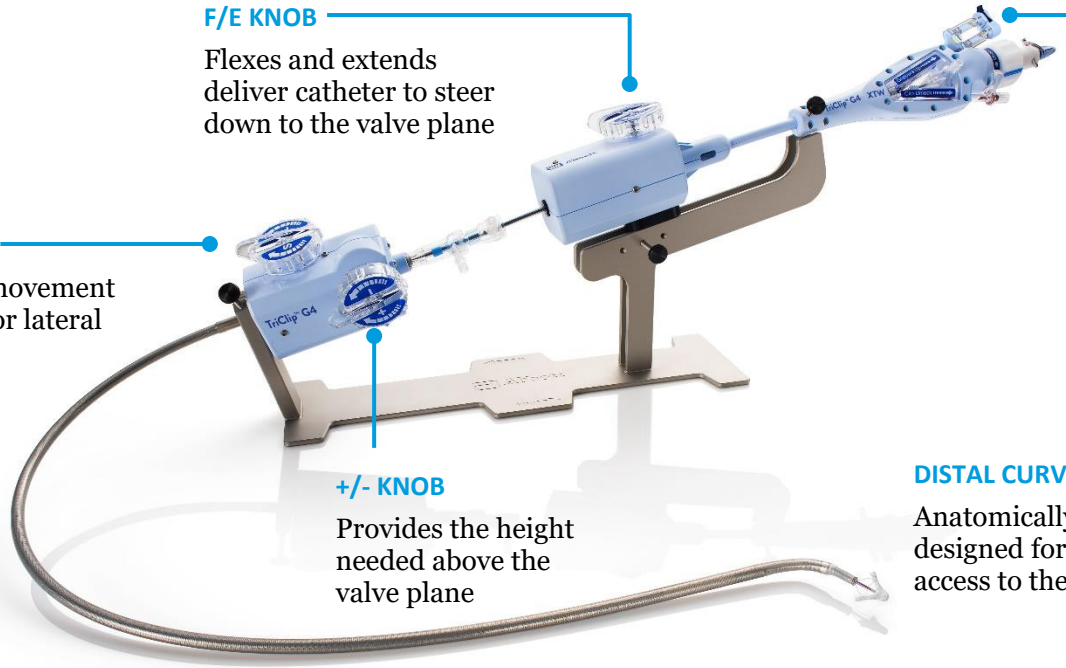
A NEW TREATMENT OPTION FOR SEVERE, SYMPTOMATIC PATIENTS AT HIGH RISK FOR SURGERY

F/E KNOB

Flexes and extends deliver catheter to steer down to the valve plane

CONTROLLED GRIPPER ACTUATION

Able to optimize leaflet grasping



S/L KNOB

Enables movement in septal or lateral direction

+/- KNOB

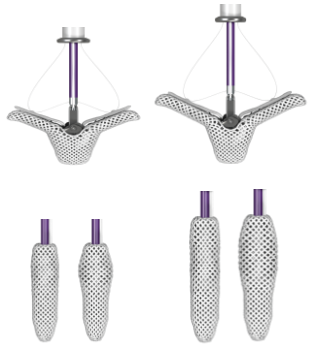
Provides the height needed above the valve plane

DISTAL CURVE

Anatomically designed for direct access to the valve

Tailor Repair with Four Sizes

NT/NTW **XT/XTW**

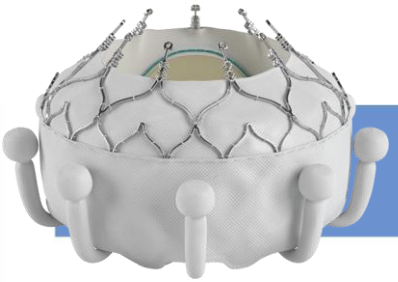


Keio University
1858
CALAMVS GLADIO FORTIOR

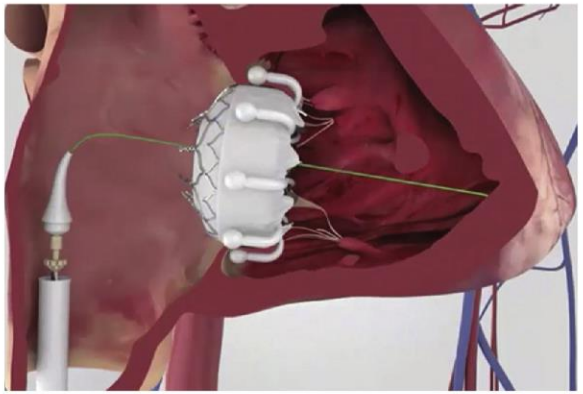
The 1st case of TriClip G4 @KEIO 2022/3/1

Keio University
1858
CALAMVS GLADIO FORTIOR

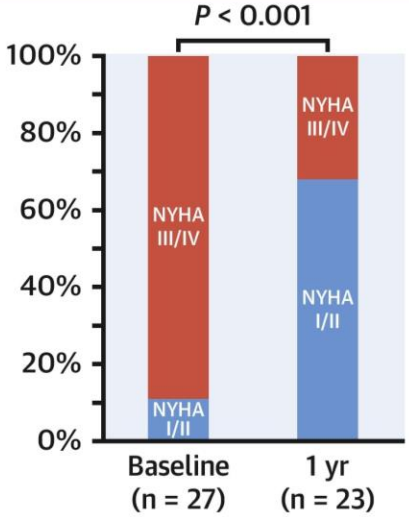
EVOQUE transfemoral tricuspid replacement 1-year outcome

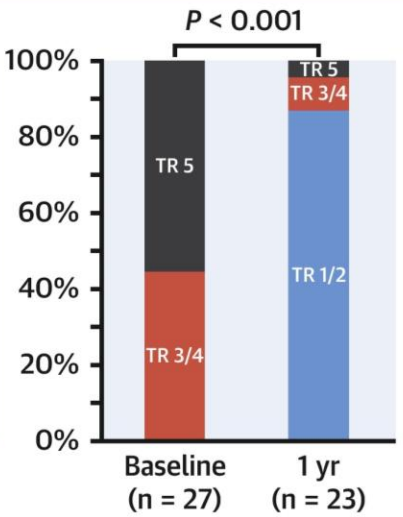


EVOQUE Transfemoral Tricuspid Replacement
1-Year Clinical and Echocardiographic Outcomes



1-Year Follow-Up





27 patients with severe TR
treated with the EVOQUE system
7 sites (Canada, Europe, U.S.)
May 2019 to July 2020

All-cause mortality: 7%
HF hospitalization: 7%
New pacemaker: 7% within 30 days,
4% beyond 30 days

Sustained improvement in NYHA functional class as well as improvement in TR degree suggesting that the EVOQUE System is a promising treatment option for this population

Webb et al. JACC 2022

Keio University
1858
CALAMVS GLADIO FORTIOR

The 1st case of TTVI in Japan 2023/3/28

Keio University
1858
CALAMVS GLADIO FORTIOR